Psychotropic medication optimisation in adults with intellectual disability

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Subsidiary supervisors: André Strydom
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Declaration

I, Neil Rory Sheehan, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

21.07.20

Neil Rory Sheehan

Date
Abstract

Background The need to improve the quality of psychotropic medication prescribing for adults with intellectual disability is reflected in Government policy. Medication optimisation is a multi-faceted approach that aims to ensure the safest, most effective, and least wasteful use of prescribed medication.

Aim To investigate the application of medication optimisation to psychotropic medication prescribing for adults with intellectual disability.

Methods 1) Multi-stakeholder qualitative study including adults with intellectual disability, paid and family carers, and psychiatrists. Data were collected in individual semi-structured interviews or focus groups and analysed using thematic analysis.

2) Systematic review and meta-analysis of peer-reviewed research reporting delivery and outcomes of psychotropic medication review. Studies were identified by searches of electronic databases, assessed independently, and appraised according to standard quality checklists.

3) Single-arm feasibility study of a structured web-based psychotropic medication review tool in community psychiatric services for adults with intellectual disability.

Results 1) Psychotropic medication use can be a contentious topic. Collaborative medication decisions are achievable, but not always experienced by adults with
intellectual disability and carers. Factors operating at individual, relational, and systems levels influence opportunities for stakeholder involvement in medication decision-making.

2) Psychotropic medication review is associated with reduction in medication prescribing but clinical, patient-reported, and economic benefit has not been consistently demonstrated. Quality of evidence is variable and studies are at risk of bias.

3) Feasibility metrics demonstrate that a definitive future trial of a medication review tool is possible. Participants made suggestions for future tool development.

Conclusions

Forms of shared decision-making can be further developed to ensure that adults with intellectual disability and their carers are involved in psychotropic medication discussions and decisions. Structured psychotropic medication review offers a potential practical means of improving the quality of psychotropic medication use and outcomes may be tested in a full-scale clinical trial.
Impact statement

This work can impact 1) the academic community, 2) clinicians, health service commissioners and policymakers, and 3) adults with intellectual disability and their families and carers.

Academic impact

I used qualitative methods and combined the perspectives of multiple stakeholders to explore decision-making processes for psychotropic medication in adults with intellectual disability. This work has added to, and extended, the relatively sparse literature in the field and can serve as a stimulus for further empirical study. I analysed my findings with reference to the shared decision-making (SDM) model. This adds to the conceptual understanding of medical decision-making in people with intellectual disability and may be applicable to healthcare decisions in this group beyond psychotropic medication. Furthermore, the discussion of SDM in people with intellectual disability may be of relevance more broadly to other groups of people with cognitive deficits or neurodegenerative disorders.

I have presented and discussed the work in this thesis at local, national and international academic conferences, and published three original papers in open-access peer-reviewed journals (Altmetric scores 18,13 & 12, January 2020).
Professional and health services impact

The findings of this work are directly relevant to health services and patient care. I conducted the first systematic review of focused psychotropic medication review, a clinical intervention that has been widely promoted but the outcomes of which are uncertain. I have been able to categorise the main types of psychotropic medication review and describe their components. The synthesis of outcomes of psychotropic medication review can inform the research agenda and guidelines for clinical practice.

I investigated the use of a novel web-based medication review tool that has the potential to harness the benefits of health information technology and promote patient and carer involvement in medication discussions. My feasibility study provides insights for development of the tool specifically and will inform later-stage work to determine its efficacy. The study also contributes generic learning points which will be of benefit for those developing and testing complex interventions in community services for adults with intellectual disability.

The findings of this work have implications for the Stopping the Over-Medication of People with learning disabilities (STOMP) programme and the future vision of healthcare for people with intellectual disability as set out in the NHS Long Term Plan.
**Patient and public impact**

This work is important in promoting and providing an empirical basis to calls to enhance the voice of people with intellectual disability and their carers in healthcare discussions and decisions. The findings, their dissemination, and future work arising from this project, can further this agenda.

I was invited to discuss my work in a podcast by the British Institute of Learning Disabilities (BILD). I ran a workshop for parent carers of people with intellectual disability at the Challenging Behaviour Foundation National Strategy Group, and for professionals at the BILD Restraint Reduction Network. Over the coming months I will continue dissemination to people with intellectual disability and their supporters.
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**Upgrade examiner:** Professor Paddy Stone

**Consultation group:** Brendan Leahy, Jackie McMorrow, Jill Huntesmith, and all other members Camden Disability Action advocacy group.

**Other:** Clinicians and NHS services that took part in the feasibility study.

Organisations that assisted in recruiting participants to the qualitative study.
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List of abbreviations

CDS – clinician decision support
CFIR – consolidated framework for implementation research
CGI-I – clinical global impression-improvement
CI – confidence interval
CINAHL – cumulative index to nursing and allied health literature
CP – consultant psychiatrist
CSV – comma-separated values
DDD – defined daily dose
EMBASE – excerpta medica database
FC – family carer
HT-SMR – HealthTracker™-structured medication review
ID – intellectual disability
IQ – intelligence quotient
IQR – inter-quartile range
MEDLINE – medical literature analysis and retrieval system online
MEI – modified efficacy index
NHS – National Health Service
NICE – National Institute for Health and Care Excellence
NIHR – National Institute for Health Research
PC – paid carer
PDA – patent decision aid
POMH-UK – prescribing observatory for mental health – United Kingdom
POTR – profile of treatment response
PRISMA – preferred reporting Items for systematic reviews and meta-analysis
SD – standard deviation
SDM – shared decision-making
SMI – severe mental illness
STOMP – stopping the over-medication of people with learning disabilities
TIDieR – template for intervention description and replication
RCT – randomised controlled trial
TP – trainee psychiatrist
UCL – University College London
UK – United Kingdom
UKMI – United Kingdom Medicines Information
Statement of personal contributions

I wrote the application for funding and was awarded an NIHR Doctoral Research Fellowship to undertake the work included in this thesis (ref: DRF-2016-09-140).

I applied for and obtained NHS ethics and local Research and Development approval for the qualitative study, recruited participants, undertook all individual interviews, and facilitated the focus groups. I transcribed the audio-recorded data, independently coded the transcripts, and led the analysis. I wrote-up the findings and submitted the report for publication.

I conducted the literature searches for the systematic review and screened the titles, abstracts, and full-text articles, as appropriate. I extracted data from the included studies, conducted the study quality ratings, and synthesised the findings, including conducting the meta-analysis. I wrote-up the findings and submitted the paper for publication.

I established a research collaboration with Professor Paramala Santosh at King’s College London. I obtained NHS ethics and local Research and Development department approvals for the medication review feasibility study, recruited clinical services and participants, trained clinicians in using the medication review tool, and oversaw the conduct of the study. I devised the feedback exercises and analysed data from the study. I wrote-up the findings and submitted the paper for publication.
I wrote all of the thesis content.
Patient and public involvement

My original interest in psychotropic medication use for people with intellectual disability was stimulated, in large part, by daily interactions with patients, carers, and health service staff in the course of my clinical work as a psychiatrist. Through these interactions I became acutely aware that issues around psychotropic medication use, including decisions to start, stop, or change medication, were important yet often fraught.

As part of the public dissemination of work prior to this Fellowship, I had many conversations which provided initial ideas for the current project. These ideas were shaped by later discussions with the Camden Advocacy Project, a local intellectual disability service-user forum.

For the purposes of this research, I recruited a Patient and Public Involvement consultation group comprising two adults with intellectual disability (who had lived experience of mental illness, psychotropic medication use and/or contact with mental health services) and a group facilitator who was known to the individuals with intellectual disability. I convened several meetings with the group over the course of the research and members contributed ideas on the design and conduct of the research. More specifically, the group helped to develop the recruitment strategy for the qualitative study and feasibility studies, assisted in the design and wording of all participant materials and easy-read information, helped to devise the patient outcome measure for the feasibility study, and gave other general advice and ideas.
to keep the research grounded and responsive to patient concerns. The group will play a role in future dissemination activities which I am currently planning.
Thesis summary

In this thesis I use different research methodologies to investigate psychotropic medication optimisation for adults with intellectual disability.

In the first chapter, I define key terms and concepts, provide an overview of importance and relevance of this work, and argue for the need to develop new and sustainable methods to improve psychotropic medication prescribing for adults with intellectual disability.

The original work comprises three studies. The first, reported in chapters 2 and 3, is a multi-stakeholder qualitative study in which I first present an inductive analysis of experiences of psychotropic medication use and decision-making in adults with intellectual disability. I interpret findings with reference to the shared decision-making model and I then explore factors that can promote or inhibit shared forms of decision-making in this context.

In chapter 4, I review the literature to describe how psychotropic medication review, often cited as part of a medication optimisation programme, has been operationalised, and appraise the evidence for the outcomes of this intervention. This is followed in chapter 5 by a clinical study conducted in community psychiatry of intellectual disability teams in which I test the feasibility of introducing a novel, structured method of psychotropic medication review.
In the final chapter I summarise the main findings of the studies and discuss their meaning for psychotropic medication optimisation in adults with intellectual disability. Throughout the thesis, implications for practice and suggestions for future work are discussed.
Chapter 1: Introduction and definition of concepts

1.1 Intellectual disability

1.1.1 Definition

People with intellectual disability have deficits in global cognitive functioning and adaptive life skills which arise in the developmental period (<18 years) (American Psychiatric Association, 2013). The term intellectual disability (used in research and internationally) is synonymous with learning disability (commonly used in UK clinical services). The International Classification of Diseases, 11th Revision uses the term ‘disorder of intellectual development’ (World Health Organization, 2020). An older term, mental retardation, is now seen as pejorative and has largely been abandoned.

People with intellectual disability are a highly heterogeneous group and individuals with the condition have wide spectrum of abilities and presentations. Intellectual disability has typically been categorised by degree based on intelligence quotient (IQ), as measured by standardised psychometric testing. Using such a classification, intellectual disability varies through mild (IQ 50-70, accounting for approximately 85% cases), moderate (IQ 35-50, 10%), severe (IQ 20-35, 4%), and profound (IQ<20, 1%). However, classification by IQ alone has been criticised as arbitrary and reductive and is giving way to a multi-dimensional system (Carulla et al., 2011) based either on severity of deficits in adaptive functioning (American Psychiatric Association, 2013) or on the type and intensity of supports that are needed (Schalock et al., 2010).
1.1.2 Epidemiology

Intellectual disability has a number of causes including genetic disorders, which may be inherited or arise de novo (e.g. Down syndrome, Fragile X syndrome), adverse in utero conditions (e.g. maternal infection or substance misuse), peri-natal complications (e.g. hypoxia and birth trauma), and significant adverse events in infancy or childhood that disturb normal brain development (e.g. CNS infection or severe abuse and neglect). In most cases, however, the underlying cause of intellectual disability is not known (Strømme & Hagberg, 2000).

A highly-cited meta-analysis of epidemiological studies by Maulik et al estimated a worldwide prevalence of intellectual disability of a little over 1% (Maulik et al., 2011). An update to this review that included 19 new eligible studies (most focused on children and adolescents) concluded that the global prevalence of intellectual disability may be lower than 1%, while noting heterogeneity in prevalence estimates across studies (McKenzie et al., 2016). Studies have consistently shown a preponderance of intellectual disability in males (Tarpey et al., 2009) and those living in low-income countries or belonging to lower socio-economic groups (Durkin, 2002; Emerson & Hatton, 2008), highlighting both the biological and social determinants of the condition. In 2015 the English Learning Disabilities Observatory estimated the number of adults with intellectual disability in England to be just under one million, although the majority were not formally recorded as having intellectual disability and were not known to statutory services (Hatton et al., 2016).
The prevalence of intellectual disability in Western countries appears to be rising, possibly as an artefact of greater recognition, but also likely as a result of immigration, improved neonatal care and greater survival of very pre-term infants, and increases in life-expectancy (Bourke, 2016; Emerson & Hatton, 2008).

1.1.3 People with intellectual disability in society

1.1.3.1 Historical context

The health and care of people with intellectual disability needs to be understood in an historical context. The past several decades have witnessed major changes in social attitudes towards, and visibility of, people with intellectual disability in the UK.

During the Victorian period and early half of the 20th Century, people with intellectual disability were viewed as either morally deficient or a threat to society. A custodial approach to management saw most placed in large, sex-segregated, long-stay institutions. The notion of people with intellectual disability as fundamentally inferior culminated in the eugenics movement which gained a widespread following across North America, Western Europe, and the Nordic countries in the 1930s. Proponents of this philosophy argued that people with intellectual disability should not be permitted to reproduce, and many were subject to programmes of involuntary sterilisation (Tilley et al., 2012). The Second World War witnessed atrocities in Nazi Germany, including the systematic extermination of people with disabilities. These events ultimately contributed to the discrediting and decline of the eugenics movement, although it was still some time before the social status of people with intellectual disability improved significantly.
Through the 1960s and 70s, a number of factors prompted significant changes in social policy towards people with intellectual disability. First, there was public outcry following the exposure of widespread abuse and neglect in residential care institutions (by then under National Health Service (NHS) management), including at Ely, South Ockendon, and Normansfield hospitals. Second, influential and, at the time, quite radical social theories of ‘normalisation’ and ‘social role valorisation’ emerged in Scandinavia and North America, which promoted the active inclusion of people with intellectual disability in mainstream society (Nirje, 1970; Wolfensberger, 1972). Third, and more prosaically, the high cost to the state associated with housing many thousands of people in institutions for the duration of their lives was felt to be unsustainable.

The UK Government White Paper ‘Better Services for the Mentally Handicapped’ outlined a desire to expand social services provision and increase the number of people with intellectual disability living in the community (Department of Health, 1971). The resulting deinstitutionalisation movement saw the number of hospital beds for people with intellectual disability fall dramatically, from over 60,000 in the 1960s to approximately 2,500 at present (Hamlin, 2008; Local Government Association et al., 2015).

1.1.3.2 Current UK policy

More recent Government policy has furthered the ambitions of Better Services for the Mentally Handicapped and aims to embed the principle self-determination
across all areas of a person’s life and ensure access to the same services and opportunities as other citizens (Department of Health, 2001a, 2009). The Disability Discrimination Act (HM Government, 1995), superseded by the Equality Act (HM Government, 2010), and the United Nations Convention on the Rights of Persons with Disabilities (UN General Assembly, 2007), have placed in statute these aspirations. Most adults with intellectual disability in the UK now live in a range of community settings with varying levels of support. Many lead independent and fulfilling lives, including having relationships and families, engaging in leisure pursuits, and are in paid or voluntary employment. Nevertheless, people with intellectual disability can still face stigma, discrimination, and restricted life opportunities (Emerson & Baines, 2011; Hatton & Emerson, 2015; Mencap, 1999). They also experience significant health inequalities and worse health outcomes, including premature deaths (Heslop et al., 2014).

1.1.4 Mental health of people with intellectual disability

Historically, intellectual disability and mental illness were considered mutually-exclusive conditions (Harris, 2006). However, we now know that the full range of psychiatric disorders may be experienced by people with intellectual disability, and indeed, that many occur at higher rates compared with the general population (Buckles et al., 2013). Cooper and colleagues undertook a population-based study in Scotland which involved direct psychiatric assessment of over 1,000 adults with intellectual disability. This revealed the point-prevalence of clinician-diagnosed mental ill-health to be 40.9%, including autism and problem behaviours, or 22.4%, excluding autism and challenging behaviours (Cooper et al., 2007). More recently,
the same group analysed data from the 2011 Scottish Census and found that people with intellectual disability were seven times more likely to self-report (or their caregiver to proxy-report) a current mental health condition than those in the comparison group without intellectual disability (Hughes-McCormack et al., 2017).

Despite its increased prevalence, mental illness can be difficult to diagnose in people with intellectual disability owing to atypical presentations, difficulty in distinguishing developmentally-appropriate behaviour from psychopathology, lack of verbal communication, and reduced ability of people with intellectual disability to recognise and describe complex and subjective internal states (Sinai et al., 2010). Furthermore, it can be problematic to apply standard diagnostic criteria and psychopathology rating scales that have been developed and normed in the general population (Levitas et al., 2004; Rush et al., 2004; Sovner & Hurley, 1983). The presentation of mental illness in people with intellectual disability may be subject to diagnostic overshadowing, whereby signs and symptoms are attributed to the intellectual disability, rather than a treatable cause, leading to further under-recognition and potential under-treatment (Reiss & Szyszko, 1983).

1.1.5 Challenging behaviour

In addition to the increased rate of mental illness experienced by people with intellectual disability is an increased likelihood to present with behavioural issues, also referred to as challenging behaviour. The most widely adopted definition of challenging behaviour is “culturally abnormal behaviours of an intensity, frequency or duration that threatens the physical safety of the person or others, or which is
likely to seriously limit use or deny access to ordinary community facilities” (Emerson, 2001). Challenging behaviour can describe an array of presentations including aggression, property damage, self-injury, disinhibited behaviours, stereotypies, and sleep disturbance. These behaviours may arise as a result of acute or chronic illness, loneliness or boredom, or abuse and neglect, and may serve a function as a means of communication (Ali et al., 2014).

The language around this concept is sometimes contentious and other terms including ‘problem behaviour’ or ‘behaviour that challenges’ are often used, the latter highlighting the socially-constructed nature of the condition as challenging to services or carers, rather than a characteristic that is inherent to the individual or their actions.

The point prevalence of challenging behaviour in adults with intellectual disability is approximately 15% (Emerson et al., 2001), with increased rates in young adults, males, those with communication difficulties, people with co-occurring autism spectrum disorder, and certain genetic conditions such as Prader-Willi and Smith-Magenis (Arron et al., 2011; McClintock et al., 2003).

The management of challenging behaviour is the subject of the first guideline published by the National Institute for Health and Care Excellence (NICE) specifically for people with intellectual disability (National Institute for Health and Care Excellence, 2015a). This guideline emphasises holistic, multi-disciplinary assessment
and formulation, and prioritises psychosocial management interventions such as Positive Behaviour Support.

Evidence for the effectiveness of psychotropic medication in managing challenging behaviour in adults with intellectual disability is sparse and of poor overall quality (Brylewski & Duggan, 2004; Sohanpal et al., 2007; Tyrer et al., 2008). Hence, the use of antipsychotic drugs in the management of challenging behaviour is recommended only where other interventions have failed, or where risks associated with the behaviour are immediate and high (Deb et al., 2009; National Institute for Health and Care Excellence, 2015a). The use of psychotropic medication to control or subdue a person’s behaviour is particularly controversial, is off-label, and is sometimes considered a restrictive practice akin to other forms forcefully restricting a person’s liberty (Frankova, 2019).

1.2 Psychotropic medication

Psychotropic medications are any drugs which may affect the mind, emotions, or behaviour. Following their introduction in the 1950s, these compounds quickly gained widespread acceptance amongst professionals and the public (Healy, 1997). Psychotropic medications are now a mainstay of treatment for mental illness (Frank et al., 2005) and amongst the most widely prescribed medications in England (Ilyas & Moncrieff, 2012).

Despite, or perhaps because of their prevalence and rapid adoption, the use of psychotropic medication has been the focus of considerable debate (Gøtzsche et al.,
2015; Liberman, 1961). Critique of psychotropic use centres around; selective reporting and bias in drug trials, many of which are funded by the pharmaceutical industry (Turner et al., 2008); poor quality evidence of efficacy and the overstating of therapeutic benefits (Gøtzsche, 2015; Leucht et al., 2015); and the mislabelling of psychotropic medications as treatments for specific disorders that correct distinct chemical imbalances associated with mental illness (Moncrieff, 2018). Like any medication, psychotropic medications can have adverse side-effects that differ by medication type; the most common include sedation, weight gain and metabolic adverse effects, and sexual dysfunction.

1.2.1 Pharmaco-epidemiology of psychotropic medication use in adults with intellectual disability

Concerns that adults with intellectual disability receive psychotropic medication excessively and indiscriminately have existed for many years (Greiner, 1958) and recent evidence appears to substantiate these fears. A review of the literature published since 2000 reveals that between roughly one-third and one-half of adults with intellectual disability living in community settings across the developed world are prescribed psychotropic medications (table 1.1). Several of these studies show a disparity between the rate of prescription of psychotropic medication and the rate of disorder for which these medications are indicated, notwithstanding the increased rate of mental illness in this group (Gomes et al., 2019; Holden & Gitlesen, 2004; Lunsky et al., 2018).
In previous work, I used The Health Improvement Network, a large and nationally-representative primary care database, to investigate the prescription of psychotropic medication in adults with intellectual disability in the UK (Sheehan et al., 2015). Seventy percent of new antipsychotic prescriptions during the 14 year follow-up period between 1999 and 2013 were to people without a recorded diagnosis of severe mental illness. Whilst it is not possible using this data source to link prescribing to indication, independent associations of antipsychotic prescribing with records of challenging behaviour, dementia, autism spectrum disorder, and advancing age suggest significant off-label use which is largely unsupported by evidence. A similar study using primary carer data was completed by Public Health England and concluded that between 30,000 and 35,000 people with intellectual disability in England are receiving antipsychotic and/or anti-depressant medication in the absence of conditions for which they are indicated (Glover & Williams, 2015). The need to improve prescribing practices was now undisputed.
Table 1.1 Prevalence and associations of psychotropic medication use in adults with intellectual disability

<table>
<thead>
<tr>
<th>Study reference, location, and type</th>
<th>Sample and characteristics</th>
<th>Prevalence estimate of psychotropic medication use</th>
<th>Associations with psychotropic medication prescribing</th>
</tr>
</thead>
</table>
| Lunsky et al., 2018, Canada, Cross-sectional | Community-dwelling adults identified through an administrative database  
\[ n=51,881 \]
Other details not reported | 39.2% antipsychotic | ° 60% antipsychotics prescribed to those without a recorded diagnosis of SMI  
° Higher rates of antipsychotic use amongst those living in group homes |
| O'Dwyer et al., 2017, Ireland, Cross-sectional | Nationally-representative sample of older adults with ID from an administrative database  
\[ n=736 \]
Male 44.8%
Age range 31-90 yrs
Mild ID 23.9%, moderate ID 46.3%, severe/profound ID 39.8%
Independent living 16.6%, community group home 36.0%, residential care 47.4%
Mental or emotional disorder 48.2% | 59% psychotropic  
42% antipsychotic  
66% those prescribed psychotropics received psychotropic polypharmacy (≥2 psychotropic medications) | ° Living in a residential institution, having a history of a mental illness, sleep problems, and severe/profound degree of ID were independently associated with psychotropic use |
| Bowring et al., 2017, Jersey, Cross-sectional | People identified through administrative and clinical databases  
\[ n=265 \] total
Male 50.6%
Age range 18-85 yrs (mean 41.4) | 38% any psychotropic  
22% antipsychotic | ° Presence of psychiatric diagnosis, challenging behaviour, advancing age and type of residence were independently associated with psychotropic prescribing |
<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Key Findings</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheehan et al., 2015</td>
<td>Nationally-representative sample of people with ID identified through a primary care database</td>
<td>History of psychotropic medication prescribed at cohort entry 49%</td>
<td>* New antipsychotic prescribing associated with recorded presence of challenging behaviour, mental illness, autism, dementia, and advancing age</td>
</tr>
<tr>
<td>UK Cohort</td>
<td>n =33,016 Male 58% Mean age 36.3 years History of mental illness at cohort entry 21% History of SMI 7% History of challenging behaviour 25%</td>
<td>Antipsychotic at cohort entry 21%</td>
<td></td>
</tr>
<tr>
<td>Glover &amp; Williams, 2015</td>
<td>Nationally-representative sample of people with ID identified through a primary care database</td>
<td>14.4% antipsychotic</td>
<td>* Potentially-relevant indications were recorded in 41.9% those prescribed antipsychotic medication</td>
</tr>
<tr>
<td>England Cohort</td>
<td>n =17,887 Male 57.4% Other details not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hsu et al., 2014</td>
<td>People with ID living in the community identified in an administrative database</td>
<td>~20% psychotropic</td>
<td>* Females, elderly, increasing degrees of ID, and those with life-limiting ID syndromes were more likely to receive psychotropic medication</td>
</tr>
<tr>
<td>Taiwan</td>
<td>n =93,914</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Population</td>
<td>Demographics</td>
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</tr>
<tr>
<td>Tsiouris et al., 2013</td>
<td>Cross-sectional</td>
<td>People with ID living in the community identified in an administrative database</td>
<td>Male 60.1%&lt;br&gt;Mean age 49.6 years&lt;br&gt;Mild ID 27.9%, moderate ID 16.0%, severe ID 18.6%, profound ID 37.6%</td>
</tr>
<tr>
<td>Holden &amp; Gitlesen, 2004</td>
<td>Cross-sectional</td>
<td>People with ID living in the community identified in an administrative database</td>
<td>Male 52.9%&lt;br&gt;Mild ID 17.7%, moderate ID 48.3%, severe ID n = 70 (23.8%)&lt;br&gt;Profound ID n = 30 (10.2%)</td>
</tr>
</tbody>
</table>

Abbreviations: ID, intellectual disability; SMI, severe mental illness
1.2.2 Specific considerations in the use of psychotropic medication in adults with intellectual disability

Psychotropic medication prescribing for adults with intellectual disability may be complicated by several factors. First, there is little direct scientific evidence for the effects of psychotropics in people with intellectual disability who are rarely recruited to drug trials, and evidence must therefore be extrapolated from results obtained from people without intellectual disability (Feldman et al., 2014). This could be problematic given the potential differences in mechanisms and presentation of mental illness in this group, and idiosyncrasies in pharmacokinetics and pharmacodynamics that might be more common amongst people with intellectual disability, particularly those with complex multi-system genetic conditions.

Second, orthodoxy holds that people with intellectual disability are at greater risk of psychotropic medication adverse side-effects and atypical reactions. This has been postulated as secondary to having lower neuronal substrate or qualitative brain differences (Arnold, 1993). Our research group has demonstrated a greater susceptibility to movement side-effects of antipsychotic medications in adults with intellectual disability (Sheehan et al., 2017a), however, there are few other direct comparisons of rates of psychotropic adverse side-effects in people with and without intellectual disability. People with intellectual disability may not be able to recognise or communicate the presence of adverse side-effects themselves (Reiss & Aman, 1997) and neither may their support professionals (Fretwell & Felce, 2007), leading to persistence of the adverse effects and impaired quality of life.
Third, people with intellectual disability often have pre-existing conditions which the adverse side-effects of psychotropic medication can complicate. For example, antipsychotic-induced muscle rigidity can worsen cerebral palsy, and medications which reduce seizure threshold can aggravate epilepsy. Related to this is the fact that people with intellectual disability often receive multiple medications for physical and mental health problems and have complex medication regimens, increasing the risk of drug-drug interactions and cholinergic burden (Haider et al., 2014; O’Dwyer et al., 2016a; O’Dwyer et al., 2016b; Straetmans et al., 2007).

Fourth, a significant number of people with intellectual disability lack understanding of their prescribed medication and do not have capacity to consent to treatment (Bourke, 2016; Ferguson & Murphy, 2014; Smith et al., 2019). This raises ethical issues, especially where there are little data with which to predict medication response.

1.2.3 Policy and recent and current events regarding psychotropic medication use in intellectual disability

The exposure of criminal abuse of vulnerable adults with intellectual disability at Winterbourne View Hospital in a British Broadcasting Corporation Panorama programme in 2011 drew unprecedented public attention and threw a spotlight on the care and treatment of people with intellectual disability. The Government response was set out in a report entitled Transforming Care, within which wide-ranging systems problems were identified. In particular, the report authors articulated the “deep concerns about the overuse of antipsychotic and anti-
“depressant medicines” that I have previously discussed (Department of Health, 2012, p.45). With new and robust evidence from pharmaco-epidemiological studies (Glover & Williams, 2015; Sheehan et al., 2015), significant political impetus was brought to the issue, and in 2016 the Stopping the over-medication of people with learning disabilities (STOMP) initiative was launched.

Comprising a relatively small project team at NHS England, the STOMP group’s strategy was to raise awareness of psychotropic medication over-prescribing amongst a broad range of stakeholders, to challenge prescribers and care providers to act to improve the quality of prescribing, and to provide resources that empower people with intellectual disability and their carers to question medication use (Branford et al., 2019). The STOMP initiative gained publicity and prompted a range of activities on both national and local levels (e.g. Adams & Sawhney, n.d.; Royal College of Psychiatrists, 2016; Tetler, 2018). Although the STOMP programme officially ended in mid-2019, the Government’s commitment to continued improvement in psychotropic use for people with intellectual disability has been reinforced in the NHS Long Term Plan (NHS, 2019). The Learning Disability Improvement Standards, which will apply to all NHS-funded care by 2023/24, specify that Mental Health Trusts must have processes to ensure that prescribing is in line with the STOMP agenda (NHS Improvement, 2018) and elements of STOMP remain embedded within routine activities such as Care and Treatment Reviews and the Learning Disability Annual Health Check in primary care.
There appears to have been little change in the quantity of psychotropic prescribing to adults with intellectual disability following the STOMP initiative. An updated investigation of psychotropic prescribing in primary care, of which I was a part, showed that antipsychotic prescribing to people with intellectual disability fell marginally after 2016, although more fine-grained reading of the data revealed this was driven by a reduction in those with severe mental illness receiving antipsychotics and, paradoxically, that the proportion of antipsychotic prescribing in those without a recognised indication actually increased (Mehta & Glover, 2019). However these data extend only to the end of 2017 and a rapid decline in the number of practices contributing to the research database reduces the statistical precision of the findings.

Clearly there is an ongoing need to improve psychotropic prescribing practice for people with intellectual disability and to develop sustainable and scalable interventions to support this. In this thesis I will introduce the concept of medication optimisation as a framework within which to achieve the best use of prescribed medication that avoids a narrow focus on quantitative measures of medication prescribing. I will argue that the application of medication optimisation to psychototropic prescribing in adults with intellectual disability could enable greater understanding of the complex clinical and non-clinical factors that influence the use of psychotropic medications and generate understanding that ultimately lead to patient benefit.
1.3 Medication optimisation

1.3.1 Definition

The term medication optimisation lacks a single definition. NICE interpret the term very broadly to mean “the safe and effective use of medicines to enable to best possible outcomes” (National Institute for Health and Care Excellence, 2015b, p.1).

The Centre for Pharmacy Postgraduate Education present a definition which makes explicit the centrality of partnership with patients:

“[Medication optimisation is] the process by which healthcare professionals engage with individual patients to understand their views, opinions and beliefs, to share their clinical and medicines knowledge so that the most appropriate evidence-based care for each individual can be agreed” (Cutler et al., 2011, p.607).

Put simply, therefore, medication optimisation is about “getting the most from medications” (Ridge & Cripps, 2016, p.2) in a framework that actively seeks, and values, patient involvement. Medication optimisation is also mindful of economic considerations and the need to achieve value for money in resource-constrained health systems. Un-optimised medication regimes can result in extra costs, such as in hospitalisations related to prescribing or monitoring errors, or morbidity from adverse side-effects (Watanabe et al., 2018). High rates of non-adherence, particularly the case with psychotropic medication, leads to significant waste (Bulloch & Patten, 2010).
UK Medicines Information (UKMI), and NHS-based pharmacy service, have proposed that medication optimisation has three key elements; **patient safety** (avoiding harm, good medicines governance, learning from errors and incidents), **effective outcomes** (including evidence-based practice and value for money), and **patient experience** (including joint decision making, personalisation, and support for patients) (UK Medicines Information, 2012). These are similar to the foundations of medication optimisation presented by the Royal Pharmaceutical Society (Royal Pharmaceutical Society, 2013):

- Aim to understand the patient experience
- Evidence based choice of medicines
- Ensure medicine use is as safe as possible
- Make medication optimisation part of routine practice

Figure 1.1 shows how these principles are manifest in the NICE Medication Optimisation Guideline, which aims to crystallise the concept by suggesting practical steps for implementing medication optimisation in healthcare settings.
Medication optimisation encompasses a range of strategies that are directed at different stakeholders throughout the medication pathway. These include educational interventions, formularies that identify and direct prescribers to medications with greatest perceived overall values, consensus best practice guidelines, benchmarking of prescription rates for individual prescribers and regionally or nationally, and decision aids developed to enable patients to take a more active role in treatment decisions. After a medication has been prescribed, optimization includes support for adherence and medication reconciliation at points of care transition.

1.3.2 Medication review

Medication review is defined as “a structured, critical examination of a person’s medicines with the objective of reaching an agreement with the person about
treatment, optimising the impact of medicines, minimising the number of medication-related problems, and reducing waste” (Shaw et al., 2002, p.12).

Medication review, as a discrete intervention, is purported to have a role in medication optimisation by: prompting changes that maximise therapeutic efficacy; recognising and minimizing adverse side-effects; and identifying opportunities for reducing unnecessary medication use (Shaw et al., 2002).

The structure, setting, depth and scope of medication reviews varies. Four levels of medication review have been identified (table 1.2) (Shaw et al., 2002). Medication review may focus on a particular medication group (e.g. anti-hypertnesives, anti-diabetic medications) or all of a person’s medications (sometimes labelled ‘comprehensive medication review’), be targeted to a particular population (e.g. the elderly living in residential care), or undertaken at a particular point in the care pathway (e.g. at hospital admission or A&E attendance).
Table 1.2 Levels of medication review

<table>
<thead>
<tr>
<th>Medication review</th>
<th>Description</th>
<th>Example</th>
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</thead>
<tbody>
<tr>
<td><strong>Level 0</strong></td>
<td><strong>Ad hoc review</strong> Unplanned, unstructured, opportunistic review which may or may not include the patient and may not be completed by a health professional</td>
<td>A receptionist asks a single question to confirm a person’s medication</td>
</tr>
<tr>
<td><strong>Level 1</strong></td>
<td><strong>Prescription review</strong> Review of medications with access to patient notes, may or may not include the patient</td>
<td>A practice pharmacist reviews the medication list of those on polypharmacy to identify medication interactions, excess doses, or brand to generic switches</td>
</tr>
<tr>
<td><strong>Level 2</strong></td>
<td><strong>Treatment review</strong> Review by a clinical member of staff, with or without the patient</td>
<td>A specialist nurse reviews asthma medication in light of investigation results or new clinical guidelines</td>
</tr>
<tr>
<td><strong>Level 3</strong></td>
<td><strong>Clinical medication review</strong> A full, structured medication review with the patient present and access to notes and knowledge of non-drug interventions, either conducted by a single professional or as part of a multi-disciplinary team</td>
<td>A GP conducting a review of anti-depressant including indication, practical issues, response to treatment and monitoring. Includes patient education, discussion of alternative management strategies, and patient ideas, concerns and expectations.</td>
</tr>
</tbody>
</table>

Medication review presents an obvious opportunity to involve patients in a discussion about their treatment, consistent with the medication optimisation approach, although not all medication reviews include face-to-face meetings with patients. I will now provide an overview of the major models of medical decision-making, paternalism, informed choice, and shared decision-making (figure 1.2).
1.4 Models of medical decision-making

Figure 1.2 Schematic representation of the major models of medical decision-making

1.4.1 Paternalism

The traditional, paternalistic model of medical decision-making describes a process whereby a physician makes a unilateral decision about intervention or treatment based on what they believe is in the best interests of a patient. In this case, the patient is relegated to a passive recipient of care who is expected to comply with whatever decision is made. Their right to autonomy is minimized or absent. Although this used to be the dominant form of medical decision-making, social shifts, outrages conducted in the name of medical research, the rise of consumerism, and developments in case law have all contributed to changes in the nature of doctor-patient relationships and the ethical and legal imperative to involve patients in decisions about their healthcare has grown (Adshead et al., 2018; James & Quirk, 2017; Rubin, 2014).

1.4.2 Informed choice

Diagrammatically opposed to the paternalistic model is the informed choice model (also known as ‘isolated autonomy’) in which the patient assumes sole responsible for decisions. Under this model, the clinician acts only to dispense information in an
unbiased way. Thus, the patient is without guidance and the experience of the doctor
in shaping the decision is overlooked (Makoul & Clayman, 2006).

1.4.3 Shared decision-making

Often considered mid-way between the paternalistic model and the informed choice
model are shared forms of decision-making. Shared decision-making (SDM) is a
collaborative process in which patients and clinicians make decisions together based
on the best available evidence and the patient’s values, preferences and goals
(Charles et al., 1997). Under a SDM model, the experiential knowledge of the patient
and their goals are given equal value as the technical knowledge and professional
expertise and experience of the doctor. Other concepts, all of which are predicated
on the principles of self-determination, are broadly synonymous with SDM and terms
are often used interchangeably (Longtin et al., 2010). These include, ‘participation’,
‘collaboration’ and ‘involvement’ (Jørgensen & Rendtorff, 2018). SDM is an
expression of person-centred care that dovetails with the broader social movement
to increase the autonomy of people with intellectual disability that has been
described above.

SDM is a philosophy, rather than a single, clearly-defined method or mechanism of
making decisions and more recent discourse around SDM has made this clear. Elwyn
and colleagues describe flexibility within the model, with the doctor or patient
assuming different degrees of responsibility under different circumstances, and
latitude for others to be included in discussions, as necessary (Elwyn et al., 2017). In
this thesis, I use the term SDM in this broad sense, rather than to refer to a rigid procedure or set of actions.

SDM has achieved widespread attention and acceptance since it was first described in 1982 (President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 1982) such that it is now recognised as an essential and expected part of modern medicine (Greenhalgh et al., 2014) and “the right thing to do” (Coulter & Collins, 2011, p.11). However, surveys indicate that a significant number of patients, including those with intellectual disability, are not involved in decisions as much as they would like (Care Quality Commission, 2016). The proportion of people who do not feel involved in healthcare decisions is higher in people accessing mental health services compared with other branches of the National Health Service (Nuffield Trust, 2019).

Under a SDM framework, psychotropic medication is not perceived as inherently good or bad, rather its advantages and disadvantages are considered in relation to an individual’s clinical needs, preferences, and life circumstances. The NICE medication optimisation guidelines specifically mention “adopting a shared decision-making approach in a consultation to ensure that patients are able to make well-informed choices that are consistent with their values and preferences” (National Institute for Health and Care Excellence, 2015b, p.40). The accompanying Quality Standard establishes the opportunity to be involved in making decisions about their medicines as a fundamental part of guideline implementation (National Institute for Health and Care Excellence, 2016).
In addition to the ethical justification for SDM, there is developing evidence that employing a SDM approach may improve a range of generic healthcare outcomes, including patient understanding, satisfaction, treatment adherence, and trust (De las Cuevas et al., 2014; Joosten et al., 2008; Shay & Lafata, 2015; Stovell et al., 2016). However, the current evidence base to describe the impact of SDM approaches on clinical outcomes is limited by a shortage of high-quality evaluation studies, poor consensus in conceptualising and measuring SDM quantitatively, lack of consistency in outcome measures across studies, and a focus on short-term outcomes (Elwyn et al., 2015).

The research literature related to SDM in people with intellectual disability is particularly poorly developed. Studies investigating the involvement of people with intellectual disability in medical decision-making often focus on the concept of informed consent (Wark et al., 2017). Informed consent is quite different from SDM, being a narrowly-defined legal term that sets the minimum required standard of information a person should understand before agreeing to a medical intervention. The process of gaining informed consent does not require personalisation to the individual, often restricts choice to agreement or refusal with a single (clinician-determined) option, and may be seen as a ‘tick box’ exercise to protect the professional, rather than to meaningfully involve the patient (Kunneman & Montori, 2017).
1.5 Summary

In this chapter, I have defined intellectual disability and framed the condition in a social and historical context. I have presented an overview of the research evidence that adults with intellectual disability receive psychotropic medications to a degree which is disproportionate to the prevalence of mental illness for which these medications would typically be indicated. I have discussed how these findings, and other events that have shone a spotlight on the care provided to people with intellectual disability, have resulted in policy directives and a major national drive to transform care for this group, including in improving the use of psychotropic medication.

I then introduced the concept of medication optimisation and discussed the central place of patient experience and involvement in the process. I have identified medication review as a practical method which may contribute to medication optimisation and could act as an opportunity for greater patient participation in medication use, including promoting shared decision-making.

1.6 Aim and objectives

1.6.1 Overall aim

The overall aim of this thesis is to investigate how medication optimisation can be applied to psychotropic medication use in adults with intellectual disability. I focus on two aspects of medication optimisation:
a) the fundamental element of patient experience and involvement in medication use, discussions, and decisions

b) medication review as a practical method to improve medication use

I undertook three separate studies that form the basis of this thesis, a qualitative study, a systematic review, and a feasibility study.

1.6.2 Objectives

My specific objectives for each study were:

1.6.2.1 Multi-stakeholder qualitative study

- Explore experiences and views of psychotropic medication use amongst people with intellectual disability and their paid and family carers
- Consider how psychotropic medication decisions are made
- Incorporate clinician perspectives with those of other stakeholders to identify influences on reaching shared medication decisions for psychotropic medication in adults with intellectual disability

1.6.2.2 Medication review systematic review

- Explore how focused psychotropic medication review has been operationalised
- Synthesise the evidence for the role of focused psychotropic medication review in medication optimisation
1.6.2.3 Structured medication review feasibility study

- Investigate the feasibility of introducing and testing a web-based structured psychotropic medication review tool (the HealthTracker™-structured medication review) in community psychiatry of intellectual disability clinics

- Gather feedback to inform future development of the medication review tool
Chapter 2: Experiences of psychotropic medication use and decision-making for adults with intellectual disability: a multi-stakeholder qualitative study

Note

A version of this work has been published as: Sheehan, R, Hassiotis, A, Strydom, A, Morant, N. Experiences of psychotropic medication use and decision-making for adults with intellectual disability: a multi-stakeholder qualitative study in the UK. BMJ Open 2019;9:e032861 (Appendix 1).

2.1 Introduction

2.1.1 Background

As I discussed in chapter 1, the concept of medication optimisation is founded on an understanding of the patient experience and on offering shared forms of decision-making. Despite the issue of psychotropic medication prescribing to people with intellectual disability having received much attention and a number of anecdotal or first-hand reports appearing in the public domain (e.g. NHS England and NHS Improvement, 2017), there has been relatively little formal investigation of the experience of adults with intellectual disability with regards to psychotropic use or of their engagement with treatment decisions. It remains unclear, for example, how, and to what extent, the principles of SDM are applied in psychotropic medication decisions in people with intellectual disability in contemporary UK settings. Given that people with intellectual disability are often supported in many aspects of their lives, including in accessing healthcare and using medication, by paid or family carers
it is also necessary to seek their perspective in any systematic work intended to inform medication optimisation in this context (Erickson & Yang, 2019; Silka & Hauser, 1997).

In a review of the published literature, I identified eleven studies that investigate the experiences and/or attitudes of stakeholders with regard to psychotropic medication for adults with intellectual disability (table 2.1). These studies vary in their methods (from online questionnaires with predominantly quantitative analysis to semi-structured qualitative interviews) and focus but it is possible to extract some common themes from the results.

Whereas adults with intellectual disability seem to be largely unquestioning and accepting of their medication (Crossley & Withers, 2009; Hall & Deb, 2008), family and paid carers express reservations or concern about the use of psychotropic medication and its appropriateness (Edwards et al., 2017; Lalor & Poulson, 2013; Sheehan et al., 2018). Paid carers may hold more favourable attitudes towards medication than family carers (Rasaratnam et al., 2004).

Adults with intellectual disability and some carers report having few opportunities to be involved in medication decision-making. Those with intellectual disability were not obviously dissatisfied with this (Crossley & Withers, 2009; Hall & Deb, 2008; Heslop et al., 2005) but family and paid carers believe they should be more involved, and sometimes report a struggle to make themselves heard (Aman et al., 1987; Christian et al., 1999; Edwards et al., 2017; Lalor & Poulson, 2013; Sheehan et al.,
Lack of involvement of any group was often seen to be predicated on a perceived or real lack of knowledge of medication and the alternatives (Crossley & Withers, 2009; Hall & Deb, 2008; Heslop et al., 2005; Sheehan et al., 2018). Paid carers perceive deficiencies in their knowledge of psychotropic medication and commonly request more training (Aman et al., 1987; Christian et al., 1999; Lalor & Poulson, 2013; Sawyer et al., 2019; Singh et al., 1996).

However, the studies summarised above span a time-frame of over 30 years during which time health policy for people with intellectual disability, as well as the wider culture around healthcare decision-making, has changed significantly, both in the UK and further afield. Studies reporting experiences related to people residing in institutional care are less relevant to the current UK context. Other limitations of the existing literature are the reliance on survey data (six studies), which is necessarily limited in depth, and the lack of integration of findings from the different stakeholder groups within the analysis.

### 2.1.2 Aims

In this chapter I will describe a study in which I sought to explore the experiences and views of adults with intellectual disability and paid and family carers regarding psychotropic medication use, and the dynamics of medication decision-making processes with healthcare professionals.

**Note on terminology** – the term used for those in paid support roles for people with intellectual disability vary across time and place. In this thesis I use the term ‘paid
carers’ whilst recognising this is comparable with other terms such as ‘direct support workers’, ‘disability support professionals’, ‘care staff’, and ‘direct caregivers’. I use ‘family carers’ to refer to relatives who are involved in the care for an adult with intellectual disability, in whatever capacity.
<table>
<thead>
<tr>
<th>Study reference and location</th>
<th>Sample</th>
<th>Design / method</th>
<th>Major findings</th>
</tr>
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<tbody>
<tr>
<td>Predominantly people with intellectual disability</td>
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</table>
| Crossley & Withers, 2009, UK | 8 adults with intellectual disability between 31 and 66 years old living in NHS community houses and prescribed antipsychotic medication for mental illness or challenging behaviour | Semi-structured individual interviews, Data analysed using grounded theory | * Participants had limited knowledge of anti-psychotic medication yet were extremely compliant.  
* Despite experience of adverse medication side-effects, most believed medication was beneficial.  
* Participants believed they had no choice in taking medication and did not expect their opinion to be sought. |
| Hall & Deb, 2008, UK | 20 adults with intellectual disability between 32 and 61 years old, most living in residential care, prescribed psychotropic medication for challenging behaviour | Semi-structured individual interviews with mix of closed and open-ended questions, Data analysed using grounded theory | * Few people with ID were fully informed about their treatment but the majority felt medication was helpful.  
* Some expressed disadvantages of medication but there was a perceived lack of role in treatment decisions and submission to the doctor’s authority. |
| Heslop et al., 2005, UK | 21 adults with intellectual disability living with various levels of support who had been prescribed psychotropic medication and 20 of their carers | Semi-structured individual interviews, Data analysed using grounded theory | * Most people with ID had only vague knowledge of the reason they were taking medication and very few were aware of potential side-effects; most did not wish to know more.  
* People with ID believed their carer knew about their medication but carer knowledge was very varied and underpinned by poor provision of information. |
### Predominantly family carers

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Methodology</th>
<th>Findings</th>
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| Edwards et al., 2017       | 7 relatives of adults with intellectual disability who had been prescribed psychotropic medication for challenging behaviour recruited through statutory government services | Semi-structured individual interviews Data analysed using an inductive form of thematic analysis | - Psychotropic medication was viewed as necessary and of benefit when used in conjunction with other approaches to manage challenging behaviour.  
- Some participants described a top-down approach to medication decision-making and fragmented care that left them feeling powerless and unheard. Others had more positive experiences of care. |
| Sheehan et al., 2018       | 99 family carers of adults with intellectual disability and challenging behaviour recruited through the mailing list of a small national charity | Online survey with mix of closed and open-ended questions | - The use of psychotropic medication for challenging behaviour evoked complex emotional responses.  
- A minority of family carers felt fully involved in medication decision-making.  
- Some family carers described feeling marginalised, lacking necessary information, and not having influence. |

### Predominantly paid carers

<table>
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<th>Study</th>
<th>Participants</th>
<th>Methodology</th>
<th>Findings</th>
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<tr>
<td>Rasaratnam et al., 2004</td>
<td>79 paid carers and 14 family carers of adults with intellectual disability who were prescribed psychotropic medication for a range of indications, recruited through specialist mental health services</td>
<td>The Rating of Attitude to Medication Scale (developed for this study) was administered in face-to-face meetings with carers</td>
<td>- Parent carers held less favourable attitudes towards psychotropic medication than family carers.</td>
</tr>
<tr>
<td>Study</td>
<td>Location</td>
<td>Participants</td>
<td>Methodology</td>
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</table>
| Aman et al., 1987            | New Zealand| 227 paid carers of people with intellectual disability living in residential institutions | A questionnaire concerning several aspects of psychotropic medication use and carer’s perceptions was mailed to eligible staff. | ◦ A hierarchy of influence in psychotropic medication decisions was described (charge nurse>psychiatrist>psychologist>nurse>student nurse>parent/relative).  
 ◦ 85% paid carers expressed dissatisfaction with their training on psychotropic medication. |
| Singh et al., 1996           | USA        | 377 staff (nurses, psychologists, support workers) in residential institutions for adults with intellectual disability | A questionnaire (adapted from Aman et al, 1987) was sent to eligible staff.                                                       | ◦ Just over half staff reported they had input into medication decision-making.  
 ◦ Physicians were perceived to have greatest influence on psychotropic medication decisions, followed by psychologists, nurses, direct care staff, social workers, and, lastly, parents.  
 ◦ Over 80% respondents believed their training on medication-related issues was insufficient. |
| Christian et al., 1999       | USA        | 334 paid carers of adults with intellectual disability living in community settings | A survey of knowledge and opinions of psychotropic medication (based on that of Singh et al, 1996) was sent to eligible staff. | ◦ Paid carers reported that psychiatrists typically did not consult them regarding psychotropic medication decisions.  
 ◦ Psychiatrists were perceived to have the greatest influence on psychotropic medication decisions, followed by psychologists, parents, and direct support staff.  
 ◦ Two-thirds of respondents reported inadequate training in medication-related issues and 88% desired additional training. |
| Lalor & Poulson, 2013        | Ireland    | 8 paid carers of adults with intellectual disability living in residential accommodation | Semi-structured individual interviews to explore experiences of psychotropic medication                                           | ◦ Paid carers expressed concern about side-effects of psychotropic medication and use as an inappropriate substitute for psychotherapeutic interventions.  
 ◦ Staff reported feeling marginalised and powerless in decision-making which was underpinned by lack of training and perceived knowledge about psychotropic medication |
| Sawyer et al., 2019 | 152 paid carers of adults with intellectual disability living in residential accommodation | Online survey of knowledge and comfort with psychotropic medication | - The majority of paid carers reported participating in medical appointments.  
- 95% paid carers expressed a desire for additional training in psychotropic medication. |
2.1.3 Qualitative work in people with intellectual disability – overview of methodological considerations

It was previously thought that people with intellectual disability were not capable of providing informative and valid responses in qualitative interviews (Sigelman et al., 1980). However the range and volume of qualitative work that has been successfully conducted over the past several years has challenged this assumption, and such methods are increasingly recognised as essential in understanding the lives and experiences of people with intellectual disability (Beail & Williams, 2014).

Several authors have discussed the additional challenges to conducting qualitative interviews in people with intellectual disability and the practical adaptations that may be used to offset these (Coons & Watson, 2013; Hollomotz, 2018; Llewellyn, 1995). Much of this advice relates to overcoming the communication deficits often present in the group and includes the need for plain English, unambiguous question phrasing (e.g. avoiding negatively worded questions), avoiding metaphors and abstract concepts, and allowing sufficient time for an individual to process information and formulate a response. Concrete reference tools, such as picture cards, have been used as prompts to make topics more tangible and increase engagement. It is recommended that interviewers be alert to non-verbal cues that may, for example, indicate participant is uncomfortable or wishes to have a break from questioning.

As people with intellectual disability can have very different communication abilities, it is necessary to be flexible and tailor the interview to the person’s ability, for
example, by altering the depth of questioning according to the answers that an individual is able to give (Hollomotz, 2018). Whereas open-ended questions are generally preferred in qualitative studies, some people with intellectual disability may find these too unstructured and not be able to answer adequately. In these cases, judicious use of closed questioning can be more productive, although care must be taken to avoid the phenomena of acquiescence (the tendency to answer ‘yes’) and recency (where the respondent chooses the last item of a list) (Heal & Sigelman, 1995).

Data collected in qualitative interviews with people with intellectual disability may not seem to be as ‘rich’ (McVilly et al., 2008), but it has been argued that this does not mean it is of lesser value (Beail & Williams, 2014). In addition to practical difficulties with literacy and vocabulary that may be present, Booth and Booth contend that the ‘inarticulateness’ of people with intellectual disability is underpinned by factors more profound than communication deficits alone (Booth & Booth, 1996). These include “a lack of self-esteem, learned habits of compliance, social isolation or loneliness, and the experience of oppression” (Booth & Booth, 1996, p.56). It can therefore be helpful to spend some time building a relationship with the person prior to starting a formal interview, giving them the opportunity to ask questions, seek reassurance, and feel comfortable (Bogden & Bilken, 1982). Permitting interviews at the time and place of a person’s choosing, and inviting a supporter, may also be of benefit in this regard (Baxter, 2005).
2.2 Methods

This was a qualitative study in which the views and experiences of multiple stakeholders were gathered in individual semi-structured interviews conducted between January and May 2018.

2.2.1 Participants and setting

People were eligible to participate if they were: adults (≥18 years) with intellectual disability who were currently prescribed psychotropic medication and were under the care of a specialist psychiatry of intellectual disability team; family carers of adults with intellectual disability who had been prescribed psychotropic medication; paid carers who worked with adults with intellectual disability and who had experience of supporting people with psychotropic medication. Family carers could live with, or apart from, their relative with intellectual disability. Paid carers may have been employed in a variety of settings including residential homes, supported living projects, or as peripatetic (‘floating’) community support workers. Psychotropic medication was defined as any medication listed in the British National Formulary as being used for mental health disorders (Joint Formulary Committee, 2017).

The study was conducted in south-east England. Two methods of recruitment of people with intellectual disability and their carers were used. In one, a leaflet advertising the research was offered to potential participants by clinicians at appointments with a number of specialist psychiatry of intellectual disability services within the National Health Service (NHS). These clinicians made a first assessment of eligibility to take part in the research. The second recruitment method included short
presentations to community third-sector (i.e. non-statutory), care provider, and training organisations, where leaflets about the research were also distributed.

After hearing about the research via either source, the contact details of those who showed an initial interest in taking part were passed to the research team, either directly from the person themselves or, with permission, via clinical staff. Potential participants were then contacted and eligibility was confirmed by liaison with people with intellectual disability and/or carers prior to interviews being held. The cognitive ability of potential participants with intellectual disability was not formally tested (i.e. no formal measure of IQ or adaptive function was conducted). Purposive sampling was used to select participants with a range of characteristics that may be related to medication views and experiences. For people with intellectual disability this included age, gender, ethnic group, indication for psychotropic medication and medication class; for family carers, age, gender, ethnic group, degree of intellectual disability in their relative, indication for and class of medication; and for paid carers, age, gender, ethnic group, duration working with people with intellectual disability, and seniority.

Capacity to consent to taking part in the research was assessed immediately before the interview as part of the procedure of obtaining valid informed consent. This process was undertaken in accordance with the principles of the Mental Capacity Act (Department of Health, 2005) and supported by participant information sheets (Appendices 2-3). I have professional experience and training in assessing capacity, including in those with cognitive deficits, and attended a Valid Informed Consent
course (run by the local NIHR Clinical Research Network) as part of my Fellowship training programme. It was made clear to participants that their contribution was voluntary, that they could decline to take part without prejudice, and they may end an interview at any time. Written consent was received from all participants before interviews were conducted (Appendices 4-5).

People with intellectual disability and family carers were given a £20 shopping voucher as a token of appreciation for donating time to the study. Paid carers were provided with a certificate thanking them for their contribution.

2.2.2 Ethical approval

The study was approved by the London-Surrey NHS Research Ethics Committee (reference 17/LO/1365) (Appendix 6). Local Research and Development approvals were obtained prior to any research activities being undertaken.

2.2.3 Data collection

Baseline demographic and descriptive data were collected by participant report; I did not cross-check these with the clinical record or other sources of information. Qualitative data were collected in audio-recorded individual in-depth semi-structured interviews. All interviews were conducted face-to-face. Participants were able to bring other people to their interview, if they wished, and interviews were held at a time and place preferred by participants. A topic guide with open-ended questions was developed and used to provide a broad structure to the interviews whilst allowing points of interest to be pursued as they arose. Included topics were,
people’s experiences of using psychotropic medication, discussions medication with health professionals, and how decisions about medication are made (Appendices 7-9). This was informed by knowledge of the literature and by my understanding of the issues that people had highlighted in preparatory work for this project. The topic guides were discussed with the consultation group, who also provided advice on wording and phrasing. The topics covered in the interview schedule were views and experiences of using psychotropic medication, how decisions about medication had been made, the involvement of different people in this, their satisfaction, and suggestions for how the process could be better.

Paid carers reported experiences and attitudes formed from supporting several different people. All study materials for people with intellectual disability were available in ‘easy-read’ format and laminated picture cards were used (where appropriate) as prompts and to orientate interviewees. Checking and summarising content throughout the interviews gave opportunity for clarification and elaboration. Reflective field notes were made to supplement the transcripts and assist with reflexive practice and data analysis.

2.2.4 Positionality statement

I am a white British psychiatrist, trained in the UK, who has been working with adults with intellectual disability across a range of healthcare settings over the past six years. I have an academic and professional interest in the use of psychotropic medication and in ways of making medication decisions more collaborative. I have published research and opinion articles in the field of medication use for adults with
intellectual disability over the past five years, and have undertaken a range of outreach activities with people with intellectual disability and their carers over this time.

I reflect in more detail on how my positioning may have influenced each stage of the qualitative work at the end of chapter 3.

### 2.2.5 Analysis

Descriptive data were summarised and tabulated. Audio-recorded interviews and focus group discussions were transcribed verbatim, anonymised by removing any identifiable information, and the transcripts checked for accuracy. Given the relative lack of literature in the field, thematic analysis was used with an inductive orientation in which themes were derived from the data. This included familiarising myself with the data by reading and listening to the transcripts several times, initial (open) line-by-line coding of the data, collating the initial codes into potential themes, reviewing and revising the codes and thematic structure, and defining and naming the final themes, aided by writing (and re-writing) an overall ‘story’ of the meaning of the data in prose form which was later developed into the final report (Braun & Clarke, 2006). NVivo qualitative data analysis software (QSR International Pty Ltd. Version 12, 2018) was used to manage the data and facilitate the analytic processes.

Transcripts of the interviews with people with intellectual disability and their carers were analysed concurrently to build a unifying coding frame that was developed in an iterative process as additional transcripts were analysed. Independent coding of
a subset of six transcripts by members of the research team early in the analytic process, regular discussion of emerging themes and the conceptual coherence of the findings, and reflexive memos were used to enhance integrity of the analysis.

2.3 Results

2.3.1 Sample characteristics

Thirty-eight people (14 adults with intellectual disability; 12 family carers; 12 paid carers) were recruited (table 2.2). Twenty-nine were recruited from clinical services and nine from third-sector organisations. Eighteen interviews were completed at people’s home (10 people with intellectual disability; 8 family carers), 12 (all paid carers) at their place of work, 7 (3 people with intellectual disability; 4 family carers) at a university, and 1 (person with intellectual disability) at a community centre. Seven participants with intellectual disability preferred to have a companion with them in the interview (in 6 cases this was a relative and in 1 case, a professional advocate).

Participants with intellectual disability reported having been diagnosed with a range of psychiatric disorders. Most had been prescribed psychotropic medication for many years and, in some cases, for decades. None of those who participated were under a legal framework of care (e.g. Community Treatment Order or Guardianship Order).
<table>
<thead>
<tr>
<th></th>
<th>Adults with intellectual disability (n=14)</th>
<th>Family carers (n=12)</th>
<th>Paid carers (n=12)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age (SD, range)</strong></td>
<td>46.1 years (12.9, 25-68)</td>
<td>62.7 years (10.5, 42-80)</td>
<td>39.4 years (9.5, 24-55)</td>
</tr>
<tr>
<td><strong>Sex (male:female)</strong></td>
<td>9:5</td>
<td>3:9</td>
<td>6:6</td>
</tr>
<tr>
<td><strong>Ethnic group</strong></td>
<td>White n=8 Black n=2 Asian n=3 Other/mixed n=1 Not recorded n=0</td>
<td>White n=8 Black n=1 Asian n=3 Other/mixed n=0 Not recorded n=0</td>
<td>White n=7 Black n=3 Asian n=2 Other/mixed n=0 Not recorded n=0</td>
</tr>
<tr>
<td><strong>Degree of intellectual disability</strong></td>
<td>Mild n=12 Moderate n=2</td>
<td>Mild n=6 Moderate n=4 Severe-profound n=2</td>
<td>N/A²</td>
</tr>
<tr>
<td><strong>Relationship to person with intellectual disability or professional title</strong></td>
<td>N/A</td>
<td>Parent n=10 Other relative n=2</td>
<td>Support worker n=8 Managerial responsibility n=4</td>
</tr>
<tr>
<td><strong>Mean time working with people with intellectual disability (SD, range)</strong></td>
<td>N/A</td>
<td>N/A</td>
<td>9.4 years (9.0, 0.5-25)</td>
</tr>
<tr>
<td><strong>Current living arrangements</strong></td>
<td>Independent n=3 With family n=5 Shared supported living n=6</td>
<td>With family member with ID n=9 Separately from family member with ID n=3</td>
<td>N/A²</td>
</tr>
<tr>
<td><strong>Reported psychiatric diagnosis</strong>[^1][^4]</td>
<td>Severe mental illness n=6 Depression n=6 Anxiety disorder n=5 Other n=2</td>
<td>Severe mental illness n=4 Depression n=4 Anxiety disorder n=6 Other n=0</td>
<td>N/A²</td>
</tr>
<tr>
<td><strong>Autism</strong>[^1]</td>
<td>n=3</td>
<td>n=5</td>
<td>N/A²</td>
</tr>
<tr>
<td><strong>Prescribed medication</strong>[^1][^4]</td>
<td>Antipsychotic n=9 Mood stabiliser n=3 Anti-depressant n=9 Other n=3</td>
<td>Antipsychotic n=10 Mood stabiliser n=2 Anti-depressant n=9 Other n=4</td>
<td>N/A²</td>
</tr>
<tr>
<td><strong>Mean duration of psychotropic use (SD, range)</strong></td>
<td>16.8 years (14.0, 3-50)</td>
<td>13.6 years (8.0, 1-27)</td>
<td>N/A²</td>
</tr>
<tr>
<td><strong>Mean interview duration (SD, range)</strong></td>
<td>24 minutes (9.0, 11-38)</td>
<td>38 minutes (10.9, 19-55)</td>
<td>47 minutes (11.9, 31-73)</td>
</tr>
</tbody>
</table>
Abbreviations: SD, standard deviation; NA, not applicable

Information provided by family carers relates to the relative with intellectual disability

Data for paid carers were not collected as each paid carer worked with more than one individual with intellectual disability

Severe mental illness includes schizophrenia spectrum disorders and bipolar affective disorder

Cell total exceeds the number in each group as people were able to report more than one diagnosis and may have been prescribed medication from more than one psychotropic class

2.3.2 Thematic analysis

I developed three major themes in my analysis of the data from the interviews with people with intellectual disability and their carers, and present these in each sub-section below. The first theme, medication beliefs and experience, describes the first-hand experience people described of using psychotropic medication, the meanings that people give to psychotropic medication, and how their views could develop over time. The second theme, carer role, draws mainly on the interviews with paid and family carers to describe how the carer identity is constructed and how caring activities related to medication use are performed. Together, these themes provide context to the third major theme of decisional processes, in which the lived experiences of different stakeholders in the medication decision-making process are explored, including the dynamics and struggles that sometimes characterised interactions with prescribers.

Throughout the analysis I have aimed to provide a clear sense of the data by using quotes from anonymised participants who were given a number prefixed with ID (person with intellectual disability), FC (family carer), or PC (paid carer).
2.3.2.1 Medication beliefs and experience: acceptance and ambivalence

I developed this theme predominantly from interviews with people with intellectual disability and family carers as I found that paid carers were generally more hesitant in offering their personal opinions about medication, and perhaps felt less of an emotional investment in medication use. In this theme, the passive compliance of the person with intellectual disability emerged, founded on relatively limited understanding of medication, yet a strong sense of faith in medication and trust in the doctor. For family carers psychotropic medication was an emotive topic and many were ambivalent about its use. A minority of paid carers expressed concerns about potentially-inappropriate psychotropic use.

People with intellectual disability tended to focus on the tangible aspects of psychotropic medication (the taste, colour, and size of tablets) and the set of ‘rules’ that constituted their current medication routine, as one woman with intellectual disability described her medication to me: “I take [the tablets] at night-time, the little mauve ones, my big yellow ones, and my little white sleeping tablet” (ID05). There was a tacit acceptance of medication as important and necessary, even though in many cases understanding of the indication for medication and its potential effects was limited. Most people with intellectual disability characterised medication benefits in vague or generic terms (e.g. “[medication] gets me better” (ID01); “it’s helpful...for my health” (ID09); “keeps me steady” (ID13)), whilst describing adverse side-effects with more immediate and vivid language (the most commonly mentioned side-effects were sedation, weight gain, and movement problems):
“My speech got slurred...really terrible and slurred. I just couldn’t get the words out” (ID07)

“I felt groggy...like I feel like a cabbage sometimes” (ID08)

The perceived consequences of not taking medication were often described as frightening and unpredictable and included being out-of-control or “a danger” (ID10). Some feared they would “probably end up back in hospital” (ID13) if they stopped medication, experiences of which (in those who had previous admissions) were universally negative and acted as a strong motivator to keep well, which people equated with medication compliance. Although a minority of people with intellectual disability did express more critical views about medication or declared that they did not like taking it, none seriously questioned its use or believed there was an alternative:

“I don’t want to take it...I don’t like taking it, but I have to” (ID04)

“I don’t like taking medication at the best of times, but I know I’ve got to take it” (ID10)

Given the length of time that most family carers had been managing medication for their relative (an average of >13 years), they tended to describe their experience as a journey in a narrative that was often recounted with a strong emotional overlay. Many recalled that medication was first prescribed during a mental health crisis. In these difficult and stressful circumstances, which sometimes impacted their own mental health, family carers could find it difficult to make a confident decision about
medication; the imperative to act being set against a sometimes deep-rooted fear of psychotropic medications and their possible side-effects:

“In the beginning I was terrified about medication, the side-effects and everything. And also her [daughter’s] condition...It’s a really dangerous medication...I read lots of information and went on the internet, and it said lots about side-effects...But I didn’t have any way out...I was really worried and couldn’t make the decision” (FC08)

Initial reticence was often overcome when the beneficial effects of medication were observed and family carers could undergo quite major shifts in attitude:

“I’d always been quite resistant [to medication] because I’d heard about chemical coshes and all that stuff...I thought ‘[son] doesn’t need a psychotropic’...but he went onto a very low dose and it noticeably helped...Now I’m at a stage of the psychiatrist thinking we should reduce the dose, and I’m really resistant to that because it feels so helpful” (FC02)

Others’ longer-term experience of medication was less favourable. In these cases medication was variously described as ineffective, only temporarily effective (the positive effects “wearing off” (FC01) over time was a relatively common thread), or blighted by adverse physical side-effects. The potential of psychotropic medication to dull people’s cognitive faculties and render them almost incapable was expressed in various terms (e.g. “[relative] was almost like a dead person...the drugs [meant]
she was moving away from us...becoming a non-person” (FC12); “they have this vacant kind of look...staring into the horizon” (PC01); “[the medication is] a sledge hammer treatment” (PC07)). Fears about psychotropic medication were occasionally juxtaposed against the sensitivity and exceptionality of the person with intellectual disability:

“Sometimes I don’t think these tablets are for people with autism and learning disabilities at all, you know? That’s not the answer...if there’s no cure, why are you giving all this medication?” (FC03)

Some carers had witnessed multiple medication changes and had come to view medication with scepticism, as unpredictable (“like taking pot luck” FC09) or even an “experiment” (FC08 & FC12). Other concerns about medication included medication being used too readily (“[the doctors are] very quick to put them on but very slow to take them off” FC06); the absence of alternative, psychosocial interventions which were often considered more appropriate but unavailable due to resource constraints (“other things can cost money...so sometimes it’s a control medication” PC06). Considering these concerns, for many carers psychotropic medication use was an ongoing source of unease:

“I’m not happy with medication...The prescription is easy to write out... they’re writing out prescriptions all the time...He’s got no other support around these issues...it’s always just medication...not enough, err, not enough maybe talking therapy...I think there should be more done than there is” (FC03)
“Hopefully [relative will need] less medication in the future...I’m worried about the side-effects but also that she will become unwell if she stops [medication]...it’s difficult, I don’t know what will happen. There could be many problems” (FC07)

Many clung to a hope that medication could be stopped at some indeterminate point in the future:

“One day, God willing, one day...she will come out of it and the medication can stop” (FC06)

2.3.2.2 Carer role: the “front-line people”

In describing their roles in caring for a person with intellectual disability, both paid and family carers placed substantial importance on knowing and being close to the person, and the privilege that this afforded them in evaluating their wellbeing and the effects of medication. Carers also spoke of their role as advocates, ensuring that processes are centred around the person with intellectual disability and their interests are upheld, and educators, filtering and translating information.

In relation to psychotropic medication, in addition to practical, daily tasks such as collecting, storing, and giving medication to the person with intellectual disability, both family and paid carers spoke of their “integral” (PC02) role in monitoring and managing people’s health. Carers described themselves as “the front-line people,”
a unique position which gave them intimate knowledge of the person with intellectual disability and was contrasted with “short and limited” (PC05) meetings with medical professionals. Knowing the person with intellectual disability closely and over time was seen as important in view of the range of problems that were described amongst the group they supported (including physical illness, developmental disabilities, mental illness and/or behavioural problems). Given this complexity, carers perceived value in their ability to interpret subtle signs and to “build up a picture of that person and how medication interacts with them” (PC02). Family carers, in particular, described an intuitive sense of ‘knowing’ the needs of their relative:

“I’ve always had to deal with [son] not being verbal and not being able to tell me, so I had to read him by body language all through his life. I’m aware of the signs...I know if he has an infection in his nose, in his ears. I know if he has a headache...if he’s not OK...I already know” (FC04)

Carers often took a gatekeeping role in determining when to seek professional advice, and in mediating interactions between the doctor and the person with intellectual disability thereafter. Family and paid carers diverged slightly in how they positioned themselves during medical appointments. Family carers described taking a more direct approach in speaking with the doctor and acting on behalf of their relative, including, for example, one mother who attended appointments with the psychiatrist while her son waited outside the room. Paid carers, meanwhile, framed their input as “empowering” (PC09) and facilitating the person with intellectual
disability to speak for themselves, so that “if there’s something the service user wants to say, I can make sure it happens” (PC04) while mostly preferring to take a “back seat” (PC06) in appointments.

Related to this were tensions within the paid carer group related to administering psychotropic medication. Several paid carers described a degree of conflict in their role between a philosophy of promoting the autonomy of those they supported (including, for example, endorsing a person’s right not to take medication if this was a capacitous decision), and being an “auxiliary clinical person” (PC11) with responsibility for ensuring the person takes the medication as directed and reporting on adherence. This included slightly more coercive aspects of checking the person doesn’t “palm it” (PC02), or ensuing medication is taken by waiting “for ten minutes to make sure they swallow it and don’t keep it in their mouth and then just chuck it off as soon as I leave” (PC05).

Several carers spoke about a process of “translating” (PC09) information between the doctor and the person with intellectual disability, again drawing on their familiarity of the person with intellectual disability in order to relay information in an individualised and more understandable way. This role often incorporated “preparing the service user for the appointment and explaining in a very clear way what might happen” (PC04) and afterwards, reflecting with and educating the person with intellectual disability after the appointment:
“[My relative] usually says [to the psychiatrist] “it’s best if you explain this to my mum or sister because they’re good at explaining it to me”” (FC08)

“I always get questioned by my clients “What’s this pill? What’s that pill?” What I’ve done for my key clients is I’ve made a list of all the medication, and I did it in easy read….and I’ve got a table of what they do with picture…if they ever ask me what happens, I just show them and go through it with them…I will stick it up on the fridge to familiarise people with it.” (PC05)

In summary, carers viewed their role with respect to medication as both broad in scope and vital to the life of the person they supported:

“I understand that sometimes I come across overbearing, nosey, and always getting involved…but I do believe, and this is a firm belief, if I was not behind [son] and asking for him, demanding for him... he would be in a worse place now, mentally... If he didn’t have me he would definitely be worse off in all sorts” (FC09)

2.3.2.3 Decisional processes relating to psychotropic medication

In this section I describe the forms of involvement that people with intellectual disability, their family carers, and paid carers experienced and desired in medication decisions, and their feelings and responses when these differed from the decisional processes they experienced.
2.3.2.3.1 Power dynamics and “the doctor’s orders”

There was a common assumption across stakeholder groups that the psychiatric appointment was the nexus of medication decisions and that the psychiatrist has the “ultimate power” (FC02) and “final say” (PC08) in medication decision-making. Interviewees, as a whole, did not express a desire to challenge this, viewing the psychiatrist as “the expert” (FC11) who “knows best” (ID10) and “does the best for everyone who’s sick” (FC07). In cases where people did not share the psychiatrist’s opinion on medication, they relatively quickly deferred (“the medical profession probably know better….I come on-board” (PC06)) and would not act alone to change medication:

“I wouldn’t [change medication] because then if anything happened I’d be the one to blame. It says in the leaflet ‘do not stop medication unless you speak to your doctor’...sometimes I feel like doing it and I think to myself, ‘no, I’ll leave it and talk to [the psychiatrist] first’...they know better than we do” (FC03)

For many with intellectual disability the authority of the doctor was absolute and left little room for their own agency. Based on their lived experience, medication decisions were a part of life over which could exert little influence:

“I have to take my medication, I ain’t got no choice...It’s the doctor’s orders to keep on the medication...there’s not a lot you can do about it” (ID11)
“It’s the doctor’s decision [about medication]…it’s up to them” (ID01)

However some (generally those with more mild intellectual disability) obviously wanted to be involved in the medication process (e.g. “Explain what [the medication] is supposed to do…Tell me what’s going on!” ID06). Congruent with these wishes, there were some descriptions of shared medication decisions. One woman with intellectual disability, for example, described how she had jointly reached a decision about reducing her medication, explaining that “[it was] my idea…and theirs [the doctors’] too” (ID04).

The desire of both paid and the majority of family carers to be involved in medication discussions and decisions was more obvious and evident through their depictions of both positive and negative experiences of medication decision-making across time and between clinicians. Positive experiences of medication decision-making were described as collaborations, “partnerships” (FC02 & PC02) and “negotiations” (PC08) and participants often made reference to having a good working relationship with the psychiatrist. In these accounts, people valued “open discussion” (PC09), being given “time to talk” (FC10), invited to give their opinion, and being “welcomed” (PC12) and “taken seriously” (FC02) when doing so:

“It’s been a really good partnership trying to get [service user] on the right medication…It’s worked really well…I went along to see the psychiatrist, spoke to him about my concerns…and then he very quickly sent appointments through to see them. And I thought, ‘wow, he listened, took it on board, called
those people in, reviewed their medication’... The psychiatrists have been very tolerant, very patient and have listened to what we’ve been saying... So it can work” (PC02)

“A lot of doctors are open to discuss...they ask the [patient] and they ask me...and they listen” (PC06)

“[The doctor] was utterly supportive [and] took seriously what I’d said, so I trusted her...She suggested medication...it was made very clear to me what the long-term side-effects are...I wanted to give it a try, see how it goes. [I felt] no pressure...I think the professionals are very good at consulting” (FC02)

Conversely, being excluded from decisions about medication could take an emotional toll, especially on family carers who described feeling “annoyed” (FC05), “frustrated” (FC04&FC08), “angry” (FC12&FC08), or isolated:

“It’s always a bad experience when you’re not involved...I wasn’t in control of anything really, and there was no-one out there I could turn to” (FC11)

“It’s been extremely stressful...When you find out somebody’s been fiddling [with medication] behind your back and you haven’t known about it” (FC05)
2.3.2.3.2 Elements of involvement and efforts to democratise medication decisions

From respondents’ accounts of how medication decisions were made, I identified three related elements of decision-making. These were being informed, being included, and having influence (figure 2.1). In any one of these processes, patients and carers could find themselves marginalised. Many paid and family carers, and a smaller number of respondents with intellectual disability, described making efforts to change the dynamics of medication decisions with strategies aimed at democratising each of these elements.

Figure 2.1 Elements of involvement in medication decisions described by participants
A pre-requisite to involvement in the decision-making process was to be informed about medication, yet several people with intellectual disability could not recall that medication was ever spoken about by their doctor (“I don’t think [the psychiatrist] talks about medication...I ain’t got a clue” (ID02)). These experiences reinforced a sense of powerlessness as medication decisions were perceived to “just happen” (ID01). Both paid and family carers reported lacking information (“hardly ever told when people switch medication” (PC09)) and sometimes not “not knowing what’s going on” (FC05). Paid carers, particularly those working in larger organisations in which numerous people with intellectual disability were supported, worried that being “out of the loop” (PC12) left them “ill-equipped and dangerously exposed” (PC11), at once responsible for medication administration and monitoring yet without vital information of medication changes, doses, or effects.

In response, both family and paid carers, and occasionally people with intellectual disability, had made attempts to improve their knowledge about medication (and alternative treatments) by seeking information independently of the psychiatrist using a variety of sources. These included, medication leaflets, television programmes, the internet, news media, carer networks, colleagues, and formal training courses.

People with intellectual disability were often reliant on carers to help them with this in a way which recalled the role that carers themselves had described:
“My sister can come, we can look up what [the medication’s] supposed to do, so at least I get a better picture” (ID06)

Acquiring knowledge was reported by participants to improve their confidence and go some way to meet and respond to the technical expertise of the psychiatrist. Many people with intellectual disability, and some carers, however, could struggle with accessing appropriate information and were left in a relatively less powerful position as a result. None of the participants mentioned having used accessible medication information.

“Me myself is not very good in asking questions or understanding everything, so I just leave it...I can’t go on the internet...I’m not very good in reading and writing, I don’t understand everything, so that’s why I don’t bother” (FC07)

Respondents in all groups had experience of being nominally present (and informed) when medication decisions were made but not included in discussions in a meaningful sense, and having little to no opportunity to voice their concerns:

“They said “you will be going on an anti-depressant.” I didn’t know the name, then it all went cold....the next thing I knew it was in my blister pack and I’ve been taking it ever since” (ID06)

“I don’t think my opinion was asked...I was in the review but I wasn’t asked the big questions about treatment” (PC10)
Family and paid carers spoke of trying to shape the discourse in conversations with the psychiatrist and needing to have confidence to challenge their authority in order to ensure their views were heard. One relative described her assertive approach as “not muck[ing] about...If I think the doctor’s wrong, I tell ‘em, just like that” (FC01). Sometimes a dramatic “bust up” (FC09) or “battle” (FC12) with the clinical team was considered necessary and could reset the interaction in favour of a greater role for the family carer in medication decisions. At other times tenacity and continuous “pushing to be involved” (PC09) spoke of an ongoing effort to develop and maintain involvement:

“I always have to be chasing. I’m still chasing now...It shouldn’t be like that, but that’s the way it works...I think [the doctors] respect me more after, I kind of, put my foot down” (FC04)

Paid carers tended to avoid overt conflict. Instead they often relied on their accumulated knowledge of the healthcare system and ‘tricks of the trade’ to navigate to a position where they stood the greatest chance of being heard. One paid carer described the strategy involved in arranging an appointment with the psychiatrist:

“I’ll have to write [to the psychiatrist] and copy in the GP...I’ll have to be quite forceful about it. And then I’ll actually ring [the psychiatrist] and I’ll follow it up with an e-mail...We can ring the learning disability [team] secretary because we’ve got a very good relationship with her...I will actually sometimes
say to her, “it’s quite a complex case this is, it’s probably worth us seeing the consultant”” (PC08)

The final element to being involved that was described by respondents was the ability to influence decisions about medication. This constituted moving beyond merely exchanging information and expressing their views to becoming a meaningful collaboration partner, whose opinions were heard and shaped decisions. Although there were clear instances where this had been achieved, all three stakeholder groups described situations in which this had not happened. Some also described strategies they had used in attempts to increase their decisional influence.

The minority of people with intellectual disability who had attempted to assert themselves were generally not successful in gaining the greater involvement and influence they wanted. In response to questioning their medication, some people with intellectual disability described receiving evasive answers that served solely to reinforce the importance of taking medication as directed:

“I just get ignored, I feel like I’m getting ignored...when I say something about [medication], it’s basically ‘you just have to take the medication’” (ID08)

“Sometimes I do [talk to the doctor about medication] but they tend to, like, they say “we can’t really say nothing because you’ve got to take it” and they don’t really say why” (ID10)
One described having recruited a carer to advocate on their behalf, but it was more common for people with intellectual disability to accede:

“I don’t get heard out properly… [The doctor says] “Is [the medication] keeping you right?” and I just say “yeah”, but I don’t think it is. But I don’t want to argue. I don’t want to argue with them so I just say “yeah, it works on me”…I’ve asked [the psychiatrist] before to [change medication] but she wouldn’t let me so I just let [the psychiatrist] get on with it…I just don’t say nothing ‘cos I feel like I’m not heard out” (ID08)

Similarly, carers reported that their concerns had been “not believed” (FC09) or “dismissed as trivial and unimportant” (PC09). Having proposed their own ideas about medication, some carers were given a sense that it was not their place to do so:

“The consultant was like “you’re talking rubbish”…it was like, ‘what does she know?’” (PC02)

“I suggested a medication which had been mentioned previously and I had looked up the research on it. It’s something that’s very useful for people with high levels of anxiety and I thought it might be worth trying but umm… there was a small flicker and then, like, “no, I don’t think so, where did you hear about this?” sort of thing” (FC05)
Such experiences could lead family carers to become burnt-out and resign themselves to a subordinate position. After what she described as a long and turbulent relationship with her relative’s care team, one mother reluctantly stepped back from taking a more active role in treatment decisions, stating “we’re [now] leaving it to them, I think that’s the best way” (FC06).

Given their perception of being ‘low ranked’ in the hierarchy of stakeholders and “not seen as a professional or intellectual resource” (PC11), paid carers often felt the need to prove the credibility of their knowledge in order to be heard and have influence. Investing in the relationship with the psychiatrist was felt to make this easier (“because they know me, they know my information is really important” (PC05)). Paid carers sometimes sought legitimacy by presenting themselves as objective, speaking of collecting data, and taking “a paper trail … [of] evidence” (PC08) to appointments to support their views.

2.4 Discussion

2.4.1 Principal findings

Psychotropic medication can have a number of desired and undesired effects (Morant et al., 2018). While adults with intellectual disability and carers who were included in this research generally recognised benefits of medication, they balanced these against experiences of specific adverse side-effects and often expressed more general reservations about the use of psychotropic medications. This set the basis for discussions and decisions about psychotropic medication as contentious and sometimes emotionally-charged (Rappaport & Chubinsky, 2000).
The expectations and preferences for people with intellectual disability with regard to involvement in medication decisions were often not explicitly expressed in the interviews. While a minority clearly articulated a desire to be involved, others expressed a preference to delegate the decision to trusted others. Between these poles was the majority of the group who appeared passive in, and sometimes detached from, medication decision-making. The reasons for this were not always apparent; unquestioned acceptance of medication could be related to a lack of knowledge, a strong and unwavering belief in medication as necessary and important, fear of the consequences of not taking medication (particularly admission to hospital), a deference towards authority figures, and previous experiences of paternalistic practice or coercion, all of which were expressed to some extent in the data. The findings accord with the ‘model of compliance’ formulated in one of the only other qualitative studies of the attitudes and experiences of people with intellectual disability towards their psychotropic medication (Crossley & Withers, 2009). Under this model, a lack of information about medication begets lack of understanding and knowledge, which leads to poor confidence and self-efficacy in raising medication issues with the doctor. Certainly, elements of this ring true in the interpretation of the data collected for this work.

The desire of (most) family and paid carers to take an active role in medication decisions arose from their closeness to the person with intellectual disability and the numerous roles related to psychotropic medication use for people with intellectual disability that they described undertaking. Hence, carers generally believed
themselves to be well-placed to contribute to the medication decision-making process and considered their involvement essential to achieving the best outcome for the individual they supported. Positive experiences were relayed in terms compatible with collaborative and negotiated models of shared decision-making (SDM) and, when this did not occur, participants often made attempts to assert themselves and gain position. While experiences of SDM undoubtedly did exist, these could not be taken for granted and many felt there were times when they had been excluded from decision-making. This resonates with existing literature which, drawing mainly on the experiences of family carers of people with intellectual disability, affirms carers’ wish to be involved in the healthcare decisions of those they support but highlights their frustration with services that are typically characterised as lacking in partnership working with relatives (Griffith & Hastings, 2014; Wodehouse & McGill, 2009).

The richness of the data enabled me to build a model that describes three major elements of decision-making, that is, being informed, being included, and having influence (cross-ref). My model, derived from the data collected, has parallels with guides to SDM, such as the ‘three-talk’ paradigm proposed by Elwyn and colleagues (Elwyn et al., 2017). Elwyn’s model describes a process of ‘team talk’ (where clinicians work together with patients to introduce choice, offer support, and set goals), ‘option talk’ (in which options are discussed), and ‘decision talk’ (where preferences are combined and a decision is made) to highlight the pathway of SDM. These three ‘steps’ of SDM are broadly analogous to being informed, being included, and having influence that I have drawn from the data. Such models may be useful in providing a
framework to make sense of participant accounts of medication decision-making and could form a theoretical basis on which to develop interventions to promote stakeholder involvement. However, they may also risk over-simplifying what is, in reality, a complex and dynamic process where individual preferences for involvement and the inclusion of other stakeholders are also important.

Not being involved in decision-making can result from an omission (e.g. not being told about changes to medication), or a seemingly more active process whereby people’s views or suggestions were diminished or disregarded. The former highlights that clinicians must be continually mindful to provide ongoing opportunities for people to be involved, particularly as circumstances, and people’s desire or ability to be involved, may change over time. The latter highlights the asymmetrical power relations that appear quite firmly embedded in doctor-patient-carer relationships and a form of epistemic injustice (where certain forms of knowledge are valued more highly than others) that persists despite purported shifts in the balance of power in such relationships over the past decades (Newbigging & Ridley, 2018).

Whilst some carers found it possible to gain agency in medication decisions even when this was not forthcoming, doing so was described as taking considerable effort and required resources that were not available to all stakeholders. This could serve to widen health inequalities as those who are less articulate or confident may be systemically less likely to have access to the potential benefits of SDM.
2.4.2 Strengths and limitations

The strengths and limitations of the qualitative work are presented in the following chapter.

2.5 Conclusion

Achieving optimal use of psychotropic medication can only occur when working in partnership with people with intellectual disability and their carers. Given the implications of a decision to use psychotropic medication, the strength of feeling that often accompanies psychotropic use, and the integral role of carers and supporters, frameworks such as SDM offer a possible means of ensuring that stakeholders are represented in important decisions. The present study suggests that successful collaborative decisions regarding medication are achievable but are not always experienced and attempts to gain agency are only moderately successful.

In the next chapter I describe the findings of a focused analysis of the qualitative data, with the addition of data collected in focus groups with psychiatrists, which highlights the challenges to achieving SDM with adults with intellectual disability and their carers.
Chapter 3: A multi-stakeholder qualitative study of the influences on reaching shared decisions for psychotropic medication in adults with intellectual disability

3.1 Introduction

Although SDM is promoted as an ideal that applies to all healthcare decisions and patient groups, its adoption in mental healthcare has been slow (Slade, 2017). In the previous chapters I have described how SDM approaches are given precedence in current clinical guidelines. They are generally favoured by stakeholders in the context of psychotropic medication decisions for adults with intellectual disability, yet do not seem to be routinely experienced. An appreciation of the barriers and facilitators to SDM from different stakeholder perspectives could translate to practical suggestions to improve opportunities for SDM and realise the potential benefits of the approach.

3.1.2 Aims

To explore the influences on making shared psychotropic medication decisions in adults with intellectual disability.

3.2 Methods

This chapter reports an extension of the study described in chapter 2. In this work I re-visit the data collected in individual semi-structured interviews with adults with intellectual disability and paid and family carers and add to this with data collected in focus groups with specialist psychiatrists, a triangulation approach which can promote a comprehensive understanding of the topic (Patton, 1999).
The methods of recruitment and data collection pertaining to adults with intellectual disability and carers who participated in qualitative interviews have been described in the previous chapter and are not repeated here. The following sub-sections refer to the methods used to recruit and gather data from psychiatrist participants.

3.2.1 Participants and setting

Psychiatrists were eligible to take part if they worked predominantly or wholly with adults with intellectual disability in community settings. Psychiatrists were recruited through e-mails sent via the distribution lists of regional educational and training networks. These e-mails contained brief details of the study, researcher contact details, and an invitation to participate. Those who expressed an interest in taking part were provided with a participant information sheet (Appendix 10). Written, informed consent was received from all psychiatrists, including for the use of anonymised quotations, prior to their taking part (Appendix 11).

3.2.2 Ethical approval

Ethical approval for conducting qualitative work with psychiatrists was granted as part of the NHS research ethics application detailed in chapter 2.

3.2.3 Data collection

Descriptive information about participating psychiatrists’ gender, ethnicity, current grade (consultant or trainee), and years spent working with people with intellectual
disability was obtained. Qualitative data were collected in two audio-recorded focus groups which I facilitated. Questioning was according to a topic guide (Appendix 12), but the approach taken was flexible and open. The topic guide included how psychotropic medication decisions are made, who is involved in decision-making and how psychiatrists perceive their role within this, and the opportunities and challenges to making shared or collaborative decisions in this context. Separate focus groups were conducted for consultant and staff grade doctors and for trainee doctors in order to maintain group homogeneity and because the presence of senior (or supervising) psychiatrists may have influenced responses of more junior doctors and impinged on their ability to speak freely.

3.2.4 Analysis

The analysis in this chapter draws on the entire data corpus, that is, data collected in individual semi-structured interviews conducted with people with intellectual disability, paid carers, and family carers, and data collected in two psychiatrist focus groups. Although I had noted some of the influences on SDM during my previous analysis (presented in chapter 2), this was a new thematic analysis, in which all of the data from the four stakeholder groups were considered together and used to develop a unified coding frame which underwent multiple revisions following discussion with my PhD supervisors (Braun & Clarke, 2006). In line with the aims of this chapter, the analysis undertaken was focused on parts of the data concerning barriers and facilitators to achieving shared decisions for psychotropic medication in adults with intellectual disability.
3.3 Results

3.3.1 Sample characteristics

The characteristics of people with intellectual disability and their carers recruited to the qualitative study have already been described. Fourteen psychiatrists, who worked predominantly in community mental health services for adults with intellectual disability across London and south-east of England, participated in two focus groups, which were conducted at University premises following Continuing Professional Development events. The first focus group consisted of trainee psychiatrists (n=6), the second comprised consultant and staff grade psychiatrists (n=8) (table 3.1).

<table>
<thead>
<tr>
<th>Table 3.1 Characteristics of focus group participants</th>
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<td><strong>Sex (male:female)</strong></td>
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<td><strong>Mean time working with people with intellectual disability (SD, range)</strong></td>
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<td><strong>Focus group duration</strong></td>
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Abbreviations: SD, standard deviation

3.3.2 Thematic analysis

To give context to the more focused analysis of barriers and facilitators to SDM, and balance the discussion with views of psychiatrists and other stakeholders, I first provide an overview of the overall discussion within the psychiatrist focus groups.
Given there were only two focus groups, the next section presents the broad positioning of psychiatrists in issues around psychotropic medication use, rather than an in-depth inductive qualitative analysis. I then move on to present the results of the more formal thematic analysis of influences on SDM.

As in chapter 2, major points are supported by anonymised quotations. Each participant is given a number prefixed with a code to distinguish which group they belong to; adults with intellectual disability (ID), family carer (FC), paid carer (PC), trainee psychiatrist (TP), consultant psychiatrist (CP).

3.2.2.1 Overview of psychiatrist focus group discussion

Psychiatrists were aware that use of psychotropic medication in people with intellectual disability was a contentious and potentially divisive topic. As a group, they did not view themselves as being either particularly in favour of, or against, the use of psychotropic medication; they recognised that medication could be used inappropriately but also considered it an effective and “really good, solid option” (CP06) in some cases.

Cognizant of the wider environment and critique of psychotropic medication, psychiatrists were keen that their medication decisions were “justified” (TP05) and defensible. They attempted to take a “methodical” (TP04) and linear approach to medication prescribing that started with information gathering and assessment, followed by diagnosis according to standard criteria, and treatment based on clinical guidelines. However, adopting such a scientific approach to prescribing was
described as uniquely difficult in people with intellectual disability who “don’t fit into categories” (TP03) owing to the complexity of their condition and co-morbidities. Clinical guidelines were described as “woolly” (TP03), or included people with intellectual disability only “as an addendum” (TP03), and were perceived as being of little practical help. Added to this were unpredictable responses to psychotropic medication that could “go against every bit of pharmacological knowledge that we know” (TP03). Thus, in reality prescribing was an “art” (TP02) which was acknowledged to engender variation in practice, as psychiatrists found themselves relying on “what we’ve seen anecdotally” (TP03) and their “best guess” (TP04).

In the midst of this ambiguity, psychiatrists described aiming to facilitate a “really open” (CP05) process of decision-making around the use of psychotropic medication involving “conversations” (CP06), “negotiations” (CP05) and “agreements” (CP08) with other stakeholders. However, I describe later in this chapter how psychiatrists’ overt endorsement of shared forms of decision-making was sometimes seen to conflict with other priorities.

Maintaining good relationships with family carers was considered “key” (CP05) (and more important than relationships with paid carers) and psychiatrists were sometimes prepared to prescribe medication against their instincts in the interests of reaching a shared decision. However, there were occasions where the gulf between the psychiatrist’s views and the views of carers was too wide to bridge; conscious of their accountability and “being the one in Court if something goes
wrong” (TP02), psychiatrists would then resort to formal procedures, such as “going down the Safeguarding route” (CP06) in order to enact their wishes.

In addition to these micro-social dynamics, psychiatrists also described the impact of overarching systemic factors on their practice. Chief among these was the pressures felt by psychiatrists to “medicate the system” (TP02). This pressure arose in the context of overstretched services, where “exhausted” and “desperate” (CP03) carers looked to medication as a “quick fix” (CP02). Alternatives to medication were often not available and other professionals were perceived to “take a step back” (CP08) when the psychiatrist became involved. Thus, psychiatrists found themselves assuming overall responsibility for complex and risky situations and having few management options aside from psychotropic medication.

The pressure that psychiatrists felt to prescribe psychotropic medication in acute situations was also experienced as pressure to continue medication in long-term users. Psychiatrists described reviewing people with intellectual disability who had taken psychotropic medication for decades, often without a clear indication and “completely against guidelines” (TP02). Their impulse to reduce or stop medication in such cases was often checked by their own worries about the potential adverse effects of withdrawing medication (again, founded on a lack of evidence and guidelines and previous “terrible experiences” (CP08) of attempts to reduce medication), by the attitudes of others (including people with intellectual disability) who favoured continuing medication indefinitely, and by the additional time and input that people who underwent medication reduction were felt to require but
which could not be guaranteed. These factors served to maintain the status quo in medication use, including what they believed to be poor practice and ‘over-medication’.

To summarise, the psychiatrists included in these focus groups were heavily invested in achieving the best use of psychotropic medication for their patients. In doing this, they found themselves balancing pros and cons of medication use in individual situations, often in the face of considerable uncertainty; navigating a complex social environment and weighing up various stakeholder views; and balancing risks and responsibilities, all within the confines of a resource-constrained and sometimes inflexible system.

3.3.2.2 Influences on SDM

A number of factors that could act to enhance or impede shared decision-making for psychotropic medication with people with intellectual disability and their carers were identified. I have grouped these into themes that correspond to the broad level at which they operate (figure 3.1).
Figure 3.1 Influences on shared decision-making for psychotropic medication in adults with intellectual disability
3.3.2.2.1 Individual factors

Across all stakeholder groups, individual level factors were seen as important in shaping and placing limitations on SDM practices. In particular, knowledge and understanding of medication emerged as a factor that was important in allowing entry to medication discussions. This was, in part, related to the quality and quantity of information provided, but also impacted by the perceived limitations of people with intellectual disability and mental health problems. Additionally, there was an awareness that preferences for involvement vary within and between stakeholder groups and that decision-making processes need to be flexible to take this into account.

3.3.2.2.1.1 Knowledge and understanding

A lack of knowledge and understanding about medication could disempower adults with intellectual disability and their carers and act as a barrier to SDM. This started with the inaccessible language that was often used around medication and its effects. “Long, Latin names” (PC06) that were “difficult to even pronounce” (FC12) were perceived to immediately exclude lay people and those with reduced literacy from conversations about medication. Few people with intellectual disability or carers described having been given tailored information about psychotropic medication and the resulting lack of knowledge impinged their ability to give informed consent, let alone contribute to a deeper discussion about the use of medication:
“I don’t know what there is out there...I’m not really knowing...Is there different [medication] I could use? Would another anti-depressant help me? I don’t know much about it so I can’t say yes and I can’t say no” (SU10)

Conversely, equipping oneself with information allowed people to take a greater role in medication discussions, and carers described seeking information from a variety of formal and informal sources. People with intellectual disability were often heavily reliant on their carers to explain and reinforce information about medication.

3.3.2.1.2 Perception of capability

All stakeholder groups spoke of restrictions to involvement of people with intellectual disability in psychotropic medication decisions that stemmed directly from the intellectual disability or the presence of co-morbid mental health problems. Medication could be perceived as “just a bit too complicated” (ID12), and the cognitive limitation that characterised the intellectual disability was believed by some carers to present an absolute barrier to involvement in the decision-making process:

“[Relative] has no understanding [about medication]...she wouldn’t have an opinion at all...she wouldn’t be able to comprehend” (FC12)

“I don’t think [a particular service user] could really give a reliable response to questions like “do you think your current medication is right for you?” So I don’t think he can be involved in making those [medication] decisions” (PC11)
Psychiatrists framed cognitive limitations in terms of the effect on mental capacity. Lacking capacity was not viewed by psychiatrists as an outright barrier to involving people in conversations about their medication but demanded adaptations to communication:

“They might not have capacity, but I [still] try and make it inclusive...I draw, or I use Makaton signs” (CP07)

Mental health problems could similarly impact the ability of people to take a role in medication decision-making, especially in the acute phase of an illness:

“[Relative] wasn’t in a condition to make a decision or anything. She was psychotic, out of control...out of reality...she didn’t know what was happening” (FC08)

In such situations, psychiatrists described their approach as being more directive and paternalistic:

“I think when someone’s in an acute crisis, you do tend to be a bit more like “we just need to do this”. And when they’re a bit better you can talk to them about changes or side-effects, but at some points you do just have to make a medical decision” (TP03)
3.3.2.2.1. Attitude and preference towards sharing medication decisions

There was a diversity of attitudes and preferences within stakeholder groups towards sharing psychotropic medication decisions. Although I have described how many carers of people with intellectual disability wanted, and indeed, felt it was necessary, that they were involved in deciding medication use, a minority of family carers did not expect or desire such a role:

“I trust the doctor [to make medication decisions]...the doctor knows their job. They do the best for everyone who’s sick” (FC07)

Similarly, although some people with intellectual disability wished to be involved, others actively chose to delegate medication decisions to others and willingly accepted the outcome:

“The doctor asks how I’ve been doing and I can tell them how I’ve been...[but] I’m not an expert on medication. My mum’s more of an expert on medication than I am...I leave it up to my mum and the doctor” (ID12)

“[The medications] make me better. I trust the people here [supported living]... [The doctor] would change it if it needed changing...I’m not a doctor so I wouldn’t know” (ID13)
Psychiatrists suggested that patient and carer preference for involvement in decision-making might be related to individual “cultural factors” (TP06) or “social status” (TP04), although these ideas were not further elaborated.

Psychiatrists were aware of a broader “cultural shift” (CP06) in practice towards “much more collaboration...rather than being paternalistic and autocratic” (CP05) and explicitly expressed their commitment to “absolutely” (TP02) sharing medication decisions with others. They spoke of “the default position of involving the patient as much as you can” (CP06) whilst acknowledging that preferences for involvement differed and introduced a dynamic element into the process:

“Some [carers] expect paternalism, and want you to pronounce [on medication]... and they’ll tell you “you’re the doctor”...And there are others who want to play an equal part. So all the time you’re building a picture of how you can collaborate or not” (TP06)

However, further analysis revealed the psychiatrists’ attitudes towards SDM to be more complex. Psychiatrists recognised that their prescribing privileges gave them a unique position and were the foundation of their “power base” (CP02) in a multi-disciplinary clinical team. They valued being able to use this power instrumentally, for example, to secure non-pharmacological and social interventions for patients with complex needs. Beneath their overt endorsement of SDM were reservations and uncertainty about the changes to roles and responsibilities that implementing SDM entailed:
“It’s being led a bit by what people want, but then again, how far do you get led one way or the other? People that really want medication and people that really don’t… Do you just do what they want?” (TP01)

In practice, it seemed that psychiatrists acted as arbiters of SDM, deciding on the degree of involvement to grant others. This was often based on the strength of their opinion in a given situation. Mindful of their responsibility to patients and professional accountability for decisions and outcomes, in “clear cut” (CP04) cases where they believed medication was indicated, psychiatrists were “not prepared to compromise” (TP) and would invoke statutory powers to cement their authority. In other cases, “where you might not have an [particular] opinion either way” (CP04), psychiatrists were willing to allow more “leeway” (TP03) and to cede influence to others. They generally set boundaries to this, though, and were thus still able to exert a degree of control by defining the options that were presented, “putting up barriers” (CP08) to certain choices, or by subtly directing the outcome of discussions while retaining a semblance of SDM:

“It’s how you phrase it as well, sometimes you’re like “it’s up to you, we could give [medication] a go”, and other times you’re like, “we really should give it a go”” (TP03)
3.3.2.2 Relational factors

Relationships between stakeholders emerged as a key influence on decision-making. This included both how individual interactions were played-out during the clinical consultation, how these were supported (or not) by necessary adaptations, and how longer-term relationships between stakeholders were maintained. Breaks in staff continuity, infrequent appointments, and geographical distance between stakeholders could influence opportunities for SDM. Finally in this section, the quality of relationships between paid and family carers (in those cases where both were involved) was also seen to have a significant influence on how involved each group felt able to be.

3.3.2.2.1 Consultation dynamics

As a focal point for discussions about medication and the forum where final decisions were made, the organisation and processes within the psychiatric consultation, and the extent to which these were adapted to the needs of people with intellectual disability, were fundamental in helping or hindering SDM.

For people with intellectual disability, the consultation could be a seen as “daunting” experience (PC09). One carer described the formality of the review process which was very much led by the medical team:

“The service user was brought in and asked a few questions. Then we left the panel to review the situation” (PC10)
People with intellectual disability were mindful of their limitations in this environment and often described finding it “hard to talk to the doctor” (ID05) or “not sure” (ID01) how participate in conversations about medication:

“It’s not just the [mental illness], I’ve got the learning disability too, so it’s very hard for me to understand... I’ve got it on my mind when I go into the [appointment] room but it doesn’t always come out properly... it’s just a blur for me... everything’s coming too quickly and it all gets muddled up” (ID10)

While some psychiatrists were described as making efforts to respond to a person’s communication needs, for example by using “very easy words” (PC04), there was a sense among some carers that psychiatrists “don’t ask the right questions” (PC08), don’t present information in accessible formats, and generally “could do more” (PC05) to make discussions about medication more easily accessible to people with intellectual disability. Psychiatrists sometimes felt constrained by practical and organisational issues which made it more difficult to involve people with intellectual disability:

“We’ve got so few clinic spaces, we’re limited to about half an hour... so if you want to bring in visual aids and involve [patients] as well, there just isn’t enough time... We just end up talking to the carer” (TP05)

However, creating an environment that promoted SDM was conditional on more than practical adaptations. The interactional style of the psychiatrist was believed to
set the overall ‘tone’ of the consultation as one conducive to collaborative discussion, or not:

“It just depends on people’s personalities, like who they are...One [psychiatrist] came the other day, and she was really nice. I don’t think she’d mind if we ask questions...but it can stop you from asking questions, depending on what kind of energy they’re giving out, do you know what I mean?” (PC03)

Sharing medication decisions was acknowledged to require compromise and “give and take” (TP03) between stakeholders and the true test of SDM occurred when stakeholders held differing opinions about medication. Psychiatrists believed that “most of the time you can reach a consensus” (CP05), although, as discussed in chapter 2, paid and family carers generally felt this was at the expense of their wishes, as the psychiatrist retained the “final say” (PC08) and overall authority in medication decisions.

Each group described experiences of perceived intransigence from other stakeholders which made arriving at a shared decision difficult and could lead to conflict or an “us and them situation” (CP05). Some family carers described experiences of “headstrong” psychiatrists with “fixed ideas” (FC06):

“In the beginning [the psychiatrist] wouldn’t give [any medication]...I was asking them to give her something to get her better because she was stuck and I was
suffering too...But [the psychiatrist] didn’t agree with me and gave me a hard

time...they didn’t listen to me for three months” (FC08)

The “anxiety and angst” (CP02) sometimes felt by psychiatrists in practising SDM for
psychotropic medication appeared most keenly felt in prescribing for challenging
behaviour. I have described in chapter 1 how the use of medication in the
management of challenging behaviour is sanctioned in only a minority of cases and
for a limited time. In keeping with this, psychiatrists were generally keen not to use
medication in such circumstances, yet they described often feeling “incredible
pressure” (CP03) from carers or other members of the clinical team to prescribe in
these “high intense” (CP02) and risk-laden situations. Several psychiatrists described
“relenting” (CP02) in such circumstances and prescribing medication against their
instincts in order to preserve an alliance with carers and protect relationships in the
longer term:

“[The family] wanted medication and it’s been a really hard process...we felt
that we had to [prescribe] because it was so much what the parents wanted, and we
thought if we did that then they would be more on board with looking at the rest of
the interventions we wanted to put in place” (TP01)

3.3.2.2.2 Continuity and availability of stakeholders

The desire of all stakeholders to maintain relationships spoke to the long-term nature
of care relationships in this context, with people with intellectual disability often
receiving care from mental health services over many years. Continuity of the
psychiatrist and of (paid) carers was an important factor in influencing opportunities for SDM.

Family carers, particularly, described how “getting to know the psychiatrist makes it easier” (FC11) to build a trusting and open relationship. Regular changes in the psychiatrist could act as a barrier to reaching a shared understanding of a person’s problems that inhibited SDM:

“We’ve seen various different [psychiatrists]...but that’s basically the problem... [When] we started to get a relationship with that person, they’d move on and it all starts over again...with one interview a [psychiatrist] can’t possibly understand the state of the patient or if medication is working...when you’ve got somebody who’s consistently been aware of [relative’s] condition it’s much easier” (FC12)

Likewise, psychiatrists described the consistency of their relationships with carers as an important factor in determining the extent to which they felt comfortable in sharing medication decisions:

“[It’s] to do with familiarity...you’re probably going to be a bit more directive [in medication decisions] if you’ve only just met the people you’re talking to. But I think when you’ve got a good relationship with people over the years, you feel you can trust each other” (CP08)
“A lot of turnover” (TP04) amongst paid carers meant it was not possible to include them as partners in decision-making that involves complex evaluative judgements about medication:

“What can happen is that a [paid] carer comes and says “I don’t know this person, I was just told to bring them to the appointment”. So they don’t actually know anything at all” (CP02)

Paid carers who worked in larger care provider organisations and supported different individuals found that they often “don’t even have time to meet the person” (PC01) who they accompanied to appointments prior to appointments and found it “tricky” to add to the conversation in those circumstances.

A related issue was the regularity of psychiatrist appointments as infrequent appointments limited opportunities for SDM and could disrupt relationships.

3.3.2.2.3 Paid carer – family carer relationships

The presence of multiple stakeholders extended medication discussions and management beyond the confines of the psychiatrist appointment. Ongoing relationships between paid and family carers were described as important in facilitating or hindering SDM. In cases where an individual lived in supported or residential accommodation, some family carers described an uneasy relationship and feeling excluded by paid carers “fiddling about with medication behind your back”
Furthermore, some family carers were suspicious about the motives of paid carers:

"Co-operation from the [residential home] was guarded...they were not forthcoming. I had to drag everything out of them as far as what they were doing. [They were] getting doctors in and prescribing stuff without actually telling us... it might be quite helpful in keeping them [residents with intellectual disability] quiet”

(FC12)

Conversely, a close working relationship between family and paid carers could add a valued extra element to decision-making. One paid carer described the joint deliberative process that they undertook when the option of a new medication was given:

"[The paid carers and I] came away [from the appointment] and said, as a joint decision, should we start [medication]? I was very keen to get [the paid carers’] opinions. And they didn’t all agree but I think they felt listened to…” (FC02)

In the small number of cases in this research where family carers’ relative was living in a distant geographical location, this was cited as an additional challenge to being involved in decisions.
3.3.2.3 Systems factors

Other factors that participants identified as influencing SDM operated on a much wider scale and were perceived to be largely beyond the control of individuals. A hierarchy of influence, perpetuated by the statutory powers that reside with mental health professionals, could result in the marginalisation of other stakeholders. Resource limitations were perceived to underlie the primacy of psychotropic medication in responses to mental illness or challenging behaviour and restricted treatment choices.

3.3.2.3.1 Hierarchy of influence

A hierarchy emerged which impacted the ability of different stakeholders to be involved in medication decisions. The psychiatrist was regarded as the most powerful actor in the network, a position that was reinforced by their statutory powers under the Mental Health Act. These powers could limit the willingness of other stakeholders to challenge medication decisions as they feared that too much dissent might result the person with intellectual disability “being Sectioned” (PC01) or “sent away from home” (FC06). The background threat of coercion and forced treatment was alluded to by several people with intellectual disability and served to place them in a subordinate position.

Family carers followed psychiatrists in the hierarchy of influence. Family carers were considered “very influential” (PC10) and “very strong” (CP08), not least because, in certain cases, they may also have legal authority conferred by the Court of Protection.
In contrast, paid carers reported being afforded a lower status as “just a provider” (PC08) and could feel undermined when they witnessed family carer opinions about medication being given “much more weight” (PC08) than their own. Psychiatrists, in describing potential conflicts, felt that paid carers were “more likely to back off” (CP01) than family carers who they thus described making more efforts to appease.

People with intellectual disability, despite being nominally at the centre of the discussion, often appeared absent in medication decisions, consistent with their not being included as the first step in involvement (figure 2.1).

3.3.2.3.2 Medication-centric culture

Stakeholders in all groups described a healthcare system in which psychotropic medication was viewed as “the be all and end all” (PC02). Medication was perceived as the default response to an array of problems was medication, a “quick fix” (CP02) preferred over other approaches. Many believed this was “all about money” (FC09) as psychological and social interventions were considered more costly and resource intensive. Such an unremitting focus on medication restricted the ability of any stakeholder to believe they had real choices in treatment decision-making and several vented their frustration:

“It’s Hobson’s choice...they’re told, “it’s medication [or nothing]”” (PC02)
“The guidelines assume we’ve got all of these things at the drop of a hat. Psychology, behaviour specialist, speech and language therapist – and actually we haven’t!... You end up in a position where you’re pushed to prescribe” (TP01)

A further demonstration of the medication-centric culture was the frequent long-term use of psychotropic medication, with many people in the sample having received medication for several years, if not decades. This, in itself, could confound discussions and favour continued medication use as all stakeholders worried about the potential consequences changing “the status quo” (PC02). For psychiatrists, although excess medication use was viewed as an “historical” (TP03) legacy, the uncertainty that accompanied making medication changes meant that they could be reluctant to reduce medication:

“There’s the fear that you go and reduce medication and they end up back in hospital and you’ve ruined their quality of life... they’ve relapsed and the recovery time is long” (TP03)

Myriad external influences, including changes of care staff or of the person with intellectual disability’s living or social situation, also seemed to foster reliance on psychotropic medication. Psychiatrists were hesitant to institute major medication changes concurrent with other life events. Hence, medication decisions (particularly those to reduce medication) were subject to various competing factors that constrained stakeholders. In this context review appointments could be seen as
“perfunctory” (PC07) and to “not really change anything” (PC05) in spite of any overtures that may be made to optimising medication and practising SDM.

3.4 Discussion

3.4.1 Principal findings

An appreciation of the barriers and facilitators to SDM is important if we are to promote opportunities for SDM in routine clinical practice (Frosch & Kaplan, 1999). In this work, I have identified a number of factors which influence SDM for psychotropic medication in adults with intellectual disability. Achieving shared medication decisions is subject to factors related to individuals, relationships and interactions between stakeholders, and the prevailing systems and culture within which mental healthcare is delivered.

3.4.2 Comparison with existing literature

In this chapter, I have explored the influences on SDM for a particular decision (the use of psychotropic medication) in a single patient group (adults with intellectual disability). There is no direct comparative work, however, a number of authors have reviewed the barriers and facilitators to SDM for psychotropic medication in a general adult psychiatric population (Morant et al., 2016; Pedley et al., 2018) or to SDM in psychiatric practice more generally (Alguera-Lara et al., 2017; Farrelly et al., 2016; Kaminskiy et al., 2017; Slade, 2017). In these studies it becomes clear that there are numerous inter-related influences on SDM. These are broadly consistent with my own findings and several authors have similarly conceptualised these with variations
on a ‘micro-, meso- and macro-level’ model (e.g. Huang et al., 2019; Morant et al., 2016).

Issues of mental capacity and insight may lead to questions about the capability of people with mental illness to act as valid and reliable decision-making partners (Hamann et al., 2010; Mahone et al., 2011; Shepherd et al., 2014; Younas et al., 2016). The cognitive impairments that characterise intellectual disability can act as a further potential barrier to SDM; while some believed these could be overcome with adaptations, in other cases participants believed the cognitive deficit was of a degree that precluded involvement to any extent. Assumptions of lack of ability to engage in SDM may be one reason why the concept has received such little attention in people with intellectual disability to date.

Forming an opinion about medication use is predicated on having sufficient knowledge of medication effects, adverse side-effects, and alternatives. People with intellectual disability have been demonstrated to have poor knowledge of their psychotropic medication (Arscott et al., 2000; Smith et al., 2019). Similarly, people without intellectual disability report poor understanding of psychotropic medication and a wish for more information (Barr et al., 2016; Iyer et al., 2013; Lacasse et al., 2016). Unsurprisingly, therefore, a lack of knowledge and understanding has often been highlighted as a factor that affects stakeholders’ confidence or ability to enter into medication discussions with clinicians (Pedley et al., 2018).
SDM approaches have gained much publicity and support in the scientific and medical literature, and are portrayed as “the pinnacle of patient-centred care” (Barry & Edgman-Levitan, 2012; Richards et al., 2013). However, it is recognised that the degree of involvement sought in mental health decisions varies from person-to-person (Hamann et al., 2010; Morant et al., 2018; Stewart et al., 2010; Woltmann & Whitley, 2010). The present study suggests that there are a group of people with intellectual disability, and some carers, who do welcome a greater role and more responsibility in psychotropic medication decision-making; these people may prefer a more paternalistic consultation style.

The concept of ‘optimal matches’ with regard to involvement in decision-making has been proposed whereby the clinician assesses the patient’s desired level of involvement and adapts their approach accordingly (Kiesler & Auerbach, 2006). Psychiatrists in this study spoke of routinely assessing patient and carer preference for involvement. The means by which they achieved this, however, were unclear and potentially subject to biases, not least, presumptions of patient capability as described above. Clinicians in other contexts have been found to be poor judges of patients’ actual preference for involvement (Bruera et al., 2001; Rothenbacher et al., 1997) which can lead to a mismatch between expectations and reality and can result in patient alienation, leaving people feeling either overwhelmed or excluded (Tobias & Souhami, 1993).

Psychiatrists in this study explicitly endorsed shared forms of decision-making. This is consistent with other qualitative work exploring the views psychiatrist who work
predominantly with non-intellectually disabled adults (Seale et al., 2006; Shepherd et al., 2014). However, there is a dissonance between these findings and the results of studies that explore patient and carer views and of micro-analytic studies of everyday psychiatric consultations which suggest that the principles of SDM are not routinely applied (Goss et al., 2008; McCabe et al., 2013; McCabe et al., 2002), and their purported enthusiasm possibly represents a social desirability bias. A sense amongst clinicians that they are “already doing SDM” (Farrelly et al., 2016; Légaré & Thompson-Leduc, 2014), at least to the extent that it is possible, further acts as a barrier to effective reflection and behaviour change.

A more detailed analysis of the data collected from psychiatrists revealed that psychiatrists were ambivalent about SDM and were reluctant to cede control of decisions in certain circumstances. Psychiatrist reluctance to relinquish power in medication decisions may be related to ideas of professional identity, autonomy, and accountability that could seem difficult to reconcile with SDM; at once being accountable for a decision and its consequences, yet without decisional responsibility (Chong et al., 2013a; Rise et al., 2013). SDM presumes there is a degree of clinical equipoise between available options, that is, there is no clearly superior option. Where psychiatrists do not believe this to be the case, they are likely to be wary of the clinical and medico-legal consequences of not providing their preferred treatment.

The preceding discussion, however, presupposes that psychiatrists act as gatekeepers to SDM in deciding when, and to whom, it should be offered, that is, the
power is *given* (or not) at the discretion of the psychiatrist, rather than being rightfully *taken* by the patient. This is a debasement of the principles of SDM, which maintains that parties meet on an equal footing from the outset, and highlights the persistence of structural power inequalities (favouring the doctor) in doctor-patient relationships, particularly in psychiatric settings (Kaminskiy, 2015; Morant et al., 2016). In a psychiatric context, power differentials are perpetuated by the background threat of enforced treatment and detention in hospital, which several of the participants in this research had experienced, and also by the use of more subtle forms of coercion, whereby psychiatrists discount patient or carer views, or invite people into conversations about their medication but limit the terms on which decisions are based (Pelto-Piri et al., 2019; Quirk et al., 2012).

At the heart of SDM are relationships and dynamic interactions between stakeholders, and successful SDM depends on mutuality and co-operation. Individual characteristics of the psychiatrist, including their attitude, demeanour and communication skills, were described as setting the tone of the clinical encounter and could promote or inhibit SDM. The building of therapeutic rapport has been as highlighted as an important influence in helping or hindering SDM (McCabe et al., 2013; Pedley et al., 2018). My results suggest that the psychiatric consultation, as the major forum in which final medication decisions were made, was not always oriented towards the patient and that few adaptations to the needs of people with intellectual disability were made, thereby limiting their opportunity to be involved in decision-making.
Psychotropic medication decision-making is typically described as being ‘distributed’, meaning that the decision-making is an iterative and ongoing process which occurs across time, social networks, and situations (Morant et al., 2016; Rapley, 2008). Psychotropic medication is often used for extended periods, through episodes of illness (to manage symptoms) and episodes of better health (to prevent relapse), with the relative advantages and disadvantages for individuals varying over time. In the case of psychotropic decision-making for people with intellectual disability, the decision-making may be even more widely ‘distributed’ between individuals due to the presence of family and/or paid carers who also have legitimate claims on involvement (chapter 2). Fostering and maintaining constructive working relationships between stakeholders whilst balancing the relative influence of different, and possibly conflicting, views was seen to add to the complexities of achieving SDM in this context.

Within the stakeholder network, power struggles could emerge between different actors. A hierarchy of influence was described, either explicitly or implicitly, by several of the participants and spoke to the continued dominance of paternalistic forms of practice, and what could more broadly be termed the ‘medical model’. A consequence of this is that certain information and accounts are given more value than others (that is, epistemic injustice) which limits genuinely inclusive decision-making (Stacey et al., 2016).

While it is possible that the presence of family members can decrease power imbalances experienced in the consultation by their role in acting as advocates
(Giacco et al., 2018), there is also concern that family carers may advance their own agenda and come dominate the consultation in a way which can intrude on patient autonomy (Huang et al., 2019). More work is needed to understand the dynamics of triadic medical consultations and how these can be optimised for patient benefit (Laidsaar-Powell et al., 2013).

The evaluation of medication and medication decisions in a SDM framework are based, to a large extent, on the values and goals of the patient, an appreciation of which might be difficult to gain in a single consultation with a psychiatrist who is unfamiliar with the individual, their history, and their aspirations. Continuity in staff (both paid carers and psychiatrists) permitted long-term relationships within which SDM was felt to be more easily established. Conversely, breaks in continuity could act to limit SDM (Chong et al., 2013b; Deslandes et al., 2015; Lacasse et al., 2016).

As in this study, practical aspects regarding the opportunity for discussion between the psychiatrist and other stakeholders have been recognised as influences on SDM (Delman et al., 2015; Gravel et al., 2006; Pedley et al., 2018). This includes the regularity of appointments and the available time with the psychiatrist (Légaré et al., 2008; Pedley et al., 2018; Torrey & Drake, 2010). However, there is no good evidence, from the few objective studies that have been conducted, that SDM approaches take more time than usual care (Légaré & Thompson-Leduc, 2014).

A healthcare system was described by all stakeholders in which psychotropic medication was the default response to presenting problems, despite the
reservations held by many about medication use and a preference for holistic models of understanding and treatment. This not only reinforces the need for a comprehensive programme of medication optimisation in this group but also has important implications for SDM. Choice in treatment decisions is fundamental to SDM but a strong pressure to use medication was felt by members of all stakeholder groups. Furthermore, a lack of alternative therapeutic options limited choice and stifled SDM. This situation is not unique to the care of adults with intellectual disability and lack of choice, often considered to result from resource or financial limitations, has been described as a barrier to SDM in several other studies (Farrelly et al., 2016; Pedley et al., 2018).

Psychiatrists were reluctant to make medication changes when other aspects of a person’s care, such as their support package or accommodation, were in flux, highlighting how complex and inter-related the care system is for adults with intellectual disability. Existing work highlights how setting factors and health system complexity can influence medication decision-making and contribute to the maintenance of potentially-inappropriate medication both in a general medical context (Anderson et al., 2014), and specifically in psychotropic medication used for challenging behaviour in adults with intellectual disability (Sheehan & Hassiotis, 2017b). Again, such external factors act to restrict freedom of choice in SDM and contribute to medication remaining a long-term intervention, with attendant risks and cumulative exposure to adverse side-effects. Medication use, then, can become a systems issue and, like unnecessary hospital detentions, a symptom of insufficient or inappropriate care provision.
3.4.3 Clinical implications

A number of clinical implications arise from this work. Clinicians, and others, should be wary of making assumptions about people’s ability to engage in SDM. For example, it is possible that even those who are most acutely mentally unwell are still able to be involved in SDM, given the right environment and adaptations (Hamann et al., 2006). Intellectual disability, in itself, should not be considered a barrier; even those individuals who lack capacity to make particular healthcare decisions in a legal sense can, and should, be brought into the decision-making process to the greatest extent possible (HM Government, 2005). This may require various adaptations to practice such as the provision of accessible information, flexibility in providing longer or more frequent appointments, or better ways of incorporating the skills and knowledge of carers in supporting the person with intellectual disability.

Supported decision-making is a parallel concept to SDM that has been advanced for those who lack decisional capacity. Like SDM, supported decision-making is predicated on the principles of autonomy and self-determination. It is distinct from substitute (or proxy) decision-making, whereby decision-making is transferred away from the individual and to their representative. Supported decision-making formalises the place of a network of individuals, which may consist of a family members, friends, or other trusted people, who are able to help the person to formulate and express their preferences and thus exercise their autonomy. This may include assistance in gathering information, generating preferences, or communicating these to the clinician. Clearly, many of the paid and family carers that
I interviewed were already active in such tasks and elements of this approach could inform shared approaches to decision-making in adults with intellectual disability.

Having sufficient information is a pre-requisite for SDM. Although many people with intellectual disability have poor knowledge of their medication, the extent to which this is related to the fixed cognitive deficit is not clear, as few participants in this study recalled having received any tailored or accessible information from healthcare professionals. People with intellectual disability want more information about their medication (Fish et al., 2017) but the provision of this in a way that is compatible with people’s level of understanding is far from straightforward, given the wide difference in cognitive profiles and communication preferences of adults with intellectual disability. Accessible (‘easy read’) information leaflets, although freely available on the internet, are of variable quality and may be outdated (Adams & Shah, 2016). Used indiscriminately, these resources have the potential to confuse rather than inform (Strydom & Hall, 2001) and simply providing a leaflet as a ‘one size fits all’ approach is clearly inadequate (Chinn & Homeyard, 2017). The work involved in effectively delivering health information to people with intellectual disability is significant and nuanced (Buell, 2015) and may require involvement of other members of the healthcare team, such as speech and language therapists, and more creative strategies such as audio-visual recordings. Consultation rooms should be equipped with tools that can augment communication, such as ‘Talking Mats’ (Murphy & Cameron, 2008).
More formal manualised training and educational interventions can improve the understanding that people with intellectual disability have about their medication (Ferguson & Murphy, 2014). These programmes may be used in a targeted way to maximise people’s ability to contribute to medication decisions, although are likely to be expensive and may be logistically difficult to organise. Results of the present study suggest that any educational intervention will also need to be extended to both paid and family carers, as important stakeholders in medication decisions. This is particularly important for those who may be less able to acquire information independently, for example, those who are socially-isolated or who do not have access to the internet.

Increasing inclusion of people with intellectual disability in healthcare decisions may represent a significant role change and disruption to established dynamics within doctor-patient relationships (Goldsmith et al., 2013), and some people appear not to want greater involvement and the additional responsibility that this entails. Delegating medication decisions to others is, in itself, a means of exerting control, and clinicians will need to work flexibly to ensure that people are invited to participate at a level with which they are comfortable. Determining the desired level of involvement can be difficult; there is a risk of confusing lack of knowledge or lack of experience and self-efficacy in making choices about healthcare for a true desire not to be further involved in decision-making (Fovargue et al., 2000; Myron et al., 2008). Added to this is the tendency of people with intellectual disability to acquiesce to authority figures and their wish to be seen as a ‘good’ (i.e. compliant) patient (Finlay & Lyons, 2002).
Furthermore, patient (or carer) desire for involvement in medical decision-making is not necessarily a fixed characteristic but is liable to change over time with illness stage and experience of medication use. This suggests that clinicians will need to regularly re-evaluate stakeholders’ ability and inclination to be actively involved as a routine part of practice. Developing valid and standardised measures of patient preference for involvement may be a way forward (Degner et al., 1997).

Although psychiatrists reported an overt commitment to the idea of the SDM for medication decisions, they did not always practice in a way true to its principles, for example, by deciding when and for whom SDM was appropriate. This suggests either a lack of complete understanding of the model and its implications, discomfort with submitting to a truly flattened hierarchy in medical consultations, a lack of skills to employ SDM faithfully, or a need to be further convinced of the benefits or applicability of SDM in this group. Training interventions to promote SDM for psychototropic medication management have been developed for patients (Hamann et al., 2011), health professionals (Harris et al., 2009), and patients and health professionals jointly (Loh et al., 2007; Ramon et al., 2017) but require larger-scale evaluation before widespread implementation can be recommended and similar programmes have not yet been developed for people with intellectual disability. The current work provides an initial understanding of the influences on SDM in people with intellectual disability that could be useful in adapting existing training programmes to meet the needs of this population.
The hierarchy of stakeholder influence that was inferred from the data again re-iterates the power asymmetries that pervade psychiatric care and can act against pluralistic approaches to treatment. Rebalancing these may require more radical changes. The Independent Review of the Mental Health Act, published in 2018, aims to inform changes to legislation that improve choice and secure a rights-based approach, although how and when recommendations will be enacted is still unclear (Department of Health and Social Care, 2018b).

On a more practical note, the results of this analysis and existing work suggest a number of pragmatic steps to be taken to facilitate SDM. Aiming to avoid breaks in continuity of psychiatrists or carers is important, though clearly difficult where the medical workforce, particularly trainee psychiatrists, move posts regularly and where low pay, poor job satisfaction, burnout contributes to high turnover of paid carers in adult social care (Department of Health and Social Care, 2018a). Sufficient material resource to ensure that alternatives to psychotropic medication are commissioned and available when needed are also a cornerstone of true SDM.

3.4.4 Strengths and limitations of the qualitative work

This study provides a formal exploration of the views and experiences of people with intellectual disability and their carers on a topic that has received considerable recent attention.

The in-depth semi-structured individual interviews enabled me to gain a deep and detailed understanding of the topic. The study extends the existing qualitative
literature in this field which has typically focused only on antipsychotic medication (Crossley & Withers, 2009) or medication used for behaviour that challenges (Edwards et al., 2017; Hall & Deb, 2008; Sheehan et al., 2018). Integrating the results of interviews with patients, family carers, paid carers, and psychiatrists allowed triangulation of the data and the development of broad, over-arching themes that can help in understanding the dynamics and influences involved in medication decision-making. Adaptations to the research method enabled me to gain meaningful insights into the experiences of people with (mild-moderate) intellectual disability, a group who are often excluded from wider research participation and may be considered inappropriate for in-depth qualitative investigation (Coons & Watson, 2013). A relatively large sample size for qualitative work, with respondents purposively sampled from different locations and according to demographic and clinical characteristics, adds to the breadth of the findings.

This study also had limitations. Participants were self-selecting, especially the psychiatrist group which I did not purposively sample, and may have included only those with greater confidence or those with more negative experiences; their views are not necessarily representative of a wider group of people with intellectual disability, their carers, or all psychiatrists working in the field. People with severe-profound intellectual disability with little verbal ability were not directly included and form a sub-group that are often overlooked in qualitative research (Gleason, 1993), although some of the family carers I interviewed did care for those with severe-profound intellectual disability. I did not include General Practitioners or allied health professionals who other work suggests play an important ‘background’ role in
decision-making in mental health (Chong et al., 2013a). Although the interview schedule was broad and flexible, its use in structuring the interviews may have precluded other issues from coming forth. I only interviewed people (and carers of people) who were currently prescribed psychotropic medication and under the care of specialist psychiatry teams, thereby excluding those who may have previously taken medication, been managed solely in primary care, or who may have chosen not to take medication for mental health problems when it was suggested. People in any of these groups may possess different and equally-valid perspectives on psychotropic medication and its prescribing. A carer or advocate was present in a number of the interviews with people with intellectual disability, although this was felt to be an important adaptation where people felt more comfortable in this situation, it could have influenced the nature of the discussion. On a related point, my professional background as a psychiatrist and someone with an interest in SDM may have subjectively influenced the discussion and also on the way that I read and analysed the data.

A limitation of this work is the small number of psychiatrist focus groups; more participants and additional data would enable me to generate and develop more substantial themes specifically related to psychiatrist views of prescribing and medication use. Although ground rules of confidentiality and positive regard for others’ opinions were explained at the start of the sessions, psychiatrists may have been influenced in their responses by the presence of peers. Most psychiatrists in each group were previously known to each other, which is largely unavoidable when
drawing specialist psychiatrists from a relatively small pool, but may have contributed to groupthink.

3.4.3 Future work
Observing interactions within real-world consultations through ethnographic work, for example, using conversation analysis, could lead to a more nuanced understanding of how medication discussions happen and how the consultation can be made a more collaborative space. It would also be important to include the views and experiences of members of other professional groups (e.g. psychologists and nurses) who play a role in the treatment, management, and monitoring of people with intellectual disability.

3.5 Conclusion
Identifying the influences on SDM for psychotropic medication in adults with intellectual disability can help us to develop an understanding of how the approach may be adapted to this context and implemented in routine care. My analysis highlights that achieving SDM for psychotropic medication decisions in adults with intellectual disability is dependent both on individual actions, fostering working relationships, and on creating a wider environment that supports choice and patient participation.

In the next chapter I review how structured psychotropic medication review has been incorporated into patient care and the impact of this on psychotropic medication optimisation. I then test a structured method of medication review might be used in
psychiatry appointments with adults with intellectual disability to psychiatrist appointments with people with intellectual disability. Before this, however, I reflect on the process of the qualitative work and my place as a researcher within this.

3.6 Reflexivity

Reflexivity is the active acknowledgement that the beliefs, biases, and personal experiences of the researcher will inevitably impact all aspects of the research, from formulating the question and recruiting participants, to the data that are collected and how they are interpreted (Berger, 2015). Examining one’s own positioning in the research process is considered essential in securing the credibility and trustworthiness of the research (Pillow, 2003; Willig, 2008).

3.6.1 Pre-research

My interest in psychotropic medication use arose early during my work as a trainee psychiatrist. Medication use is a very common intervention and prescribing is often seen as the preserve of the psychiatrist within a multi-disciplinary team. I have been aware of the controversies and discourse around psychotropic medication use that are played out in the media and that have formed part of my professional training, and have often considered these in situations that I encounter clinically. I have regularly needed to weigh up whether medication is the right intervention, who decides this, and what the prominence that is given to different voices when there is disagreement about whether medication is prescribed. I have reflected on where the voice of the person with intellectual disability is in this. In addition, having conducted epidemiological research on the degree of psychotropic prescribing in adults with
intellectual disability (Sheehan et al., 2015; Sheehan et al., 2017a) I became interested in the personal experiences of medication use. These experiences motivated me to explore the subject using qualitative methodology.

3.6.2 Recruitment

For ethical reasons it was not possible for me to approach people with intellectual disability or their carers about the research directly. Instead I had to identify potential participants through third-party intermediaries. This method is common in research with people with intellectual disability but can be problematic (Nind, 2008). I found that this was easier with the clinicians and clinical services that I approached, with whom I had pre-existing working relationships. I also approached third sector and care organisations to broaden the scope of recruitment but found it took time to make the necessary links and build trust with various people to gain access. Intermediaries could act as de facto gatekeepers to the research and I had several experiences where people working in services chose, either explicitly or less overtly, who was, and who was not, appropriate to take part in the research. This phenomenon is recognised in such situations and can contribute to the denial of information and choice for the person with intellectual disability (Llewellyn, 1995). On one occasion I did not recruit an adult woman with intellectual disability who had expressed a wish to take part in a research interview because on hearing about the study her parents preferred that she was not involved. It is possible that this gatekeeping restricted the range of voices that I heard.
In the recruitment phase I felt it was also necessary for me to be clear and transparent about my role and influence in people’s clinical care, especially where they had been recruited through clinical services. I took care to explain that I was independent of their healthcare and could not offer advice beyond very generic suggestions or ‘signposting’ to appropriate services. I was mindful that while some people would approach the research for purely altruistic reasons and the motivation that “it might help people in the future”, some may have been hoping that I could mediate in a current dispute or be an ally in their struggle with an aspect of their care.

3.6.3 Data collection

Several factors could have affected the nature of the data that I collected. There was a potential power imbalance between me and the research participants, particularly those with intellectual disability, who may be more used to occupying subordinate positions and where somebody in a professional role can be seen as intimidating. I was conscious of this throughout my interactions, both so that people did not feel pressure to participate and so that people were at liberty to speak openly about their experiences. It was possible that some people may have been guarded in what they said, if they perceived me as being too close to the clinical service and there may be a reluctance to criticise services for a fear they will be withdrawn (Merriman & Beall, 2009). I did not generally feel that people censored themselves, although I noted on a few occasions people would prefix a criticism of health services with “I’m sorry that they may be your colleague” or checked “this is confidential, isn’t it?”
Although I have experience of interviewing people with intellectual disability and mental illnesses and their carers across a range of settings, I found the focus of the research interview to be different and required different skills. In a clinical interview, I am used to gathering a large volume of information in a short time, integrating it with other factual and historical information, and using this to devise a plan by the end of the meeting. The research interview was far more exploratory and aimed to be largely directed by the participant. This caused me some anxiety initially as I wondered whether I was collecting ‘enough’ of the ‘right’ information. Listening back to the interview recordings I could hear my style evolving as I relaxed and gained more confidence as the project progressed.

Due to my experience working with people with intellectual disability and my research work that has focused on psychotropic medication use over in this group over the past over 5 years, and the wider conversations that have accompanied this (including with the consultation group), I felt a close relationship with the research topic and that I had some appreciation of the concepts that were important. However, I was still an ‘outsider’ in this situation, not having shared the experiences of the participants with intellectual disability or their carers, and maybe more so in those participants whose cultural and social background was different to my own. I needed to be continually mindful of this. Conversely, with in the focus groups with psychiatrists, I felt very much an ‘insider’ to the group. Berger has discussed the relative advantages and disadvantages that the “dual identity” of ‘researcher’ and ‘researched’ confers (Berger, 2015). On one hand I benefitted from a tacit understanding of the relevant issues. It is likely that my ‘insider’ status shaped the
conversation when participants may have assumed I already know some of their experience. Whilst it was not possible to mitigate or ‘bracket off’ my experience completely (Tufford & Newman, 2012), I made a deliberate effort to remain neutral and enquiring in the data collection and to remain objective in my responses to the data at the analysis stage. I did find it easier to analyse the results of the psychiatrist focus groups, partly because the volume of data was less, but also possibly because of my natural affinity with the group.

3.6.4 Data interpretation
I was aware in the analysis that the contribution of the less articulate people with intellectual disability could be overlooked in favour of those who presented a more complete and classically eloquent account and it was important to me that their contribution was given equal precedence in the analysis. Balanced against this, however, was a need to be mindful not to interpret too much from brief responses. Similarly, I was conscious that more strident views should be included and could portray certain points, but needed to be given context within the range of experiences and views that I heard.

The initial analysis benefitted from independent coding by a colleague working in a related field, and later analysis by extensive collaboration and discussion with the PhD supervisory team. Each re-organisation led to a repeat process of ‘arguing with the data’ to see that the new framework was supported, although this was a lengthy process, I now feel confident that the results accurately reflect the data.
Chapter 4: Association of focused medication review with optimisation of psychotropic medication prescribing: systematic review

Note

The content of this chapter has been published in an amended format as: Sheehan, R, Strydom, A, Brown, E, Marston, L, Hassiotis, A. Association of focused medication review with optimisation of psychotropic drug prescribing. *JAMA Network Open* 2018;1(6):e183750 (Appendix 13).

4.1 Introduction

In the first chapter of this thesis, I introduced the theoretical aspects of medication review and how medication review, as a discrete intervention, has been proposed as part of medication optimisation. However, the evidence relating to the effectiveness of the medication review is disparate and inconclusive, and the place of medication review in routine clinical practice remains unclear.

A number of systematic reviews of medication review have been published over the past five years, attesting to ongoing interest in the topic but also reflecting the lack of consensus within the scientific and clinical community. The focus of these systematic reviews varies greatly as authors specify inclusion criteria based on different types of medication review (e.g. pharmacist-led medication review (Thiruchelvam et al., 2017)), settings (e.g. hospital (Renaudin et al., 2016), residential homes, or the community (Jokanovic et al., 2016)) populations (e.g. the elderly (Kallio
et al., 2018)), or outcomes of interest e.g. reduction in particular symptoms (Hadi et al., 2014; Nakham et al., 2019), or mortality (Christensen & Lundh, 2016).

NICE reviewed the evidence for the effectiveness of medication review compared with usual care as part of the medication optimisation guideline, including only randomised controlled trials (RCTs) published after the year 2000 (National Institute for Health and Care Excellence, 2015b). The 28 studies that were included in the evidence synthesis included any type of medication review, thus, a diverse range of participants and medication review types were combined. Most were pharmacist-led medication reviews and none were reviews specifically of psychotropic medication. The clinical evidence derived from the studies was low-moderate quality, as measured with the GRADE system (Guyatt et al., 2008). Many studies included small numbers of participants or high drop-out rates and were under-powered to detect important effects. Pooling of evidence was limited as studies reported different outcome measures and follow-up times. Overall the guideline development group concluded there were “mixed findings of the effect of medication reviews compared with usual care” (National Institute for Health and Care Excellence, 2015b, p.120) and the resulting recommendation concerning medication review was necessarily vague; the committee recommended practitioners “consider carrying out structured medication review for some groups of people when a clear purpose has been identified” (National Institute for Health and Care Excellence, 2015b, p.124). They left the target group and the practicalities of medication review to be determined locally.
Huiskes et al also took a broad approach to synthesising the literature and included medication reviews that had been tested in an RCT, irrespective of patient population or outcome measure (Huiskes et al., 2017). Their analysis included 31 trials (many of which were also included in the NICE review) from which the authors concluded medication review was associated with greater change in medication and a decrease in measured medication-related problems. However, the review failed to demonstrate an effect of medication review on clinical outcomes, quality of life, or economic measures, and the authors surmised that there was insufficient evidence to perform medication reviews as part of standard care.

Despite the lack of support in the research literature, medication review has come to be seen as an important activity in the process of medication optimisation and is guideline-recommended (or mandated) under certain conditions. In the US, long-term residential care facilities must have processes to regularly review psychotropic medication prescribing (Hawes et al., 1997). In England medication review for certain groups (including the frail elderly and people receiving polypharmacy) is incentivised in primary care (BMA and NHS England, 2019; Department of Health, 2001b). Similar recommendations for conducting medication review exist in the Netherlands (van Rijn, 2016) and in Germany (Federal Association of German Pharmacists Associations, 2014).

No research has reviewed the evidence for focused psychotropic medication review, that is, medication review targeted to psychotropic medications only. There may be reason to consider psychotropic medication review separately, given that these
medications can be seen as a ‘special case’ and are often prescribed, monitored, and reviewed independently of other medications. This may arise secondary to disconnects in the organisation of physical and mental healthcare, or because non-specialist clinicians are less comfortable with reviewing and changing psychotropic medication.

4.1.2 Aims

In this chapter I describe a systematic search of the literature with the aim of exploring how focused psychotropic medication review has been operationalised in practice, and synthesise the evidence for the outcomes of this intervention.
4.2 Methods

4.2.1 Database searches and study eligibility

A systematic literature search was conducted in four electronic databases (MEDLINE, PsycINFO, EMBASE, CINAHL Plus) from inception to identify peer-reviewed original research articles that reported the impact of focused psychotropic medication review on medication optimisation outcomes. Search terms included ‘medication review’ (and synonyms) combined with ‘psychotropic’ (and synonyms) (see Appendix 14 for example full search strategy). Psychotropic medications were defined in accordance with the World Health Organisation Anatomical Therapeutic Chemical Classification System (World Health Organisation, n.d.). Medication review was defined in accordance with the UK National Prescribing Centre definition as “a structured critical evaluation of medication with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, and minimising the number of medication-related problems” (Shaw et al., 2002, p.12). Given that this is the first review and my knowledge of the state of the existing evidence, optimisation outcomes were kept intentionally broad and any study design was included. There were no restrictions on population, setting, language or date of publication. The literature search was first conducted in February 2018 and updated in August 2019 with no change to methodology.

To limit potential confounding, studies were excluded if they reported a comprehensive medication review (including multiple classes of medication simultaneously), or conducted a medication review as part of a multi-modal intervention (for example, with co-occurring educational interventions) where the
unique effect of medication review on reported outcomes could not be distinguished. Short reports, research letters, dissertations and conference abstracts were not included but prompted a search for corresponding full-length articles. Reference lists of included studies and previously-published reviews in the field were extensively hand-searched to find articles not identified in the database search. The citations of included articles were identified using Google Scholar and considered for relevance. The systematic review protocol was registered prospectively with PROSPERO (registration number: CRD42017077244).

4.2.2 Study selection
After exclusion of duplicate records, the titles of all articles were screened, and a randomly-selected sample of 5% was independently reviewed by a second member of the research team. We both independently reviewed abstracts of remaining studies (and later selected full text) against inclusion and exclusion criteria, with any discrepancies resolved by consensus or discussion with my primary supervisor. Interrater reliability was assessed at each stage study selection by calculating Cohen’s kappa (McHugh, 2012).

4.2.3 Study quality
Study quality was rated independently by myself and one other member of the research team using the relevant quality checklist published by the National Institutes of Health (National Heart Lung and Blood Institute, n.d.) (Appendices 15-16). Studies received an overall grading of poor, fair, or good quality based on the proportion of applicable checklist items that were met (poor <30%, fair 30-60%, good
>60%). In addition, I made an evaluation of the limitations of each paper which I report descriptively in the data tables. Results of the quality appraisal were used to inform a structured evidence synthesis with higher quality studies given precedence.

4.2.4 Data extraction

Data were extracted from each study and used to populate summary tables. Medication review type was classified according to the Task Force on Medicines Partnership and the National Collaborative Medicines Management Services Program (level 0, ad hoc review; level 1, prescription review; level 2, treatment review; level 3, clinical medication review) (Shaw et al., 2002). Reviews of similar type were grouped according to a categorisation that I developed based on the common features of across interventions. Outcomes were grouped according to theme allowing comparison between different studies. Measures of psychotropic medication optimization could include; changes in medication-related variables (such as dose or type of medication), clinical efficacy (according to measured symptoms) or adverse medication events, participant-reported outcomes (such as quality of life or satisfaction), or economic evaluations. Additional data were sought by contacting authors of included studies, where indicated.

4.2.5 Data analysis

Results were summarized narratively. Numerical data were extracted and means and 95% confidence intervals were calculated around summary statistics. I visualised these data as Forest plots in order to aid comparisons and interpretation of overall trends. Odds ratios for comparable outcomes reported in randomized controlled
trials were entered into a meta-analysis using the *metan* command in Stata v14 (StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP) and using a random effects model. The $I^2$ statistic was used to estimate statistical heterogeneity between studies (Higgins & Thompson, 2002).

4.3 Results

4.3.1 Eligible studies

The original database searches yielded a total of 9,464 articles of which 27 met inclusion criteria. The updated search revealed 810 new potentially-eligible articles, none of which met inclusion criteria. The results of both searches are presented in the PRISMA flow diagram (figure 4.1) and separately in Appendices 17-18. There was generally almost perfect agreement between the two raters at the level of title screening (Cohen’s $k=0.831$), moderate agreement at abstract screening ($k=0.479$), and perfect agreement at the level of full text screening ($k=1.0$) (Viera & Garrett, 2005).
Figure 4.1 PRISMA flow diagram of study identification and selection

- **Identification**: 21 additional articles identified through other sources
  - 10,274 citations identified (Medline 3257; EMBASE 3786; PsycINFO 1502; CINAHL Plus 1,729)
  - 3,282 duplicates removed
  - 7,013 titles screened
  - 6,411 citations excluded on title
  - 602 abstracts reviewed
  - 545 citations excluded on abstract
  - 57 studies for full text review

- **Eligibility**: 30 citations excluded after full text review
  - No medication review intervention (n=4)
  - Not focused psychotropic review (n=10)
  - Multi-modal intervention (n=5)
  - No optimisation outcome (n=7)
  - Short report or conference abstract (n=4)

- **Review**: 27 studies included in review (8,556 participants)
  - 3 studies included in meta-analysis (652 participants)
The results of one large study were reported in two articles (Ballard et al., 2017; Ballard et al., 2015). Four of the included studies were cluster RCTs ($n=712$ participants in total) (Ballard et al., 2017; Ballard et al., 2015; Jordan et al., 2015; Moncrieff et al., 2016; Patterson et al., 2010) and the remaining 22 were before-after study designs ($n=7,844$ participants in total) (Bach et al., 2017; Bisconer et al., 1995; Branford, 1996; Child et al., 2012; Craig & Mehta, 1984; Dahl et al., 2008; Donat, 2006; Ellenor & Frisk, 1977; Ferguson et al., 1982; Gallimore et al., 2016; Gemelli et al., 2016; Glaser & Morreau, 1986; Inoue, 1982; Jauernig & Hudson, 1995; Johnson et al., 2012; Laska et al., 1980; Lepler et al., 1993; Marcoux, 1985; Morrison, 2009; Napolitano et al., 2012; Prentice & Wright, 2014; Seltzer et al., 2000). Studies were conducted in North America ($n=15$), Europe ($n=10$) and Australasia ($n=1$). The majority of studies ($n=19$) were conducted in institutional settings and reported psychotropic medication review of people with intellectual disability ($n=9$ studies, $n=1,054$ participants) or those with dementia ($n=6$ studies, $n=3,664$ participants).

Full details of included studies are given in appendix 19. When assessed against objective criteria, most research was at medium-high risk of bias. Key methodological problems encountered across studies were single group design, reporting bias, lack of measures of implementation fidelity, lack of objective and validated outcome measures, short follow-up times, and limited (or absent) statistical analysis. Several studies made claims that were not supported by the findings, particularly when attributing medication change or other outcomes to the medication review process rather than other, extraneous factors that might have been important in these largely observational studies.
4.3.2 Content and delivery of psychotropic medication review

I developed three categories based on the broad characteristics of the focused psychotropic medication review interventions described in the eligible studies (Figure 4.2). The first was one-off medication review, usually undertaken by a single, third-party professional and including a single class of psychotropic medication. This model was more common in the recently-published literature. The second model was a longitudinal programme of regular medication reviews, often by a multi-disciplinary team who reviewed the participant’s psychotropic medication regimen over a series of meetings. These review types were more often encountered in the older literature and in congregate care settings such as long-stay residential institutions for people with intellectual disability or dementia. The third type of focused psychotropic medication review was a two-stage review, in which those at high-risk of sub-optimal medication therapy were identified using a rule applied to the electronic patient record, and then directed to clinician medication review, usually with their usual clinician (with or without senior oversight). Within this broad categorization, the configuration of focused psychotropic medication review varied, for example, in whether the patient’s full clinical notes were available and if the patient had any involvement in the process (table 4.1). Medication reviews were most often organized according to local protocols but specific conduct of the medication review was commonly not reported. The medication reviews studied were conducted by physicians (n=6 studies), pharmacists (n=4 studies), nurses (n=2 studies) or the multi-disciplinary team (n=14 studies). The most consistent staff representation in all reviews was of pharmacists (involved in 15 reviews).
Figure 4.2 Types of focused psychotropic medication review

Abbreviations: MDT, multi-disciplinary team
<table>
<thead>
<tr>
<th>Study reference</th>
<th>Participants, setting</th>
<th>Psychotropic medications reviewed</th>
<th>Professionals involved</th>
<th>Patient or patient representative involvement</th>
<th>Review delivery</th>
<th>Guidelines and instruments used</th>
<th>Review level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ballard et al., 2017; Ballard et al., 2015</td>
<td>People with dementia, nursing home</td>
<td>Antipsychotic medications</td>
<td>Physician</td>
<td>NR</td>
<td>General practitioner or psychiatrist antipsychotic review using clinical guidelines to determine appropriateness and direct withdrawal attempts</td>
<td>NICE dementia guidelines, Alzheimer’s society guidelines</td>
<td>CD</td>
</tr>
<tr>
<td>Moncrieff et al., 2016</td>
<td>People with severe mental illness, community</td>
<td>Antipsychotic medications</td>
<td>Physician Care co-ordinator (nurse, social worker, occupational therapist)</td>
<td>Yes – patient</td>
<td>Patients used a medication review tool with their care co-ordinator prior to a psychiatrist appointment. The tool incorporated perceived benefits and disadvantages of antipsychotic medications and desired changes which could be discussed with the prescriber.</td>
<td>Medication Review Tool (developed for the study)</td>
<td>3</td>
</tr>
<tr>
<td>Gallimore et al., 2016</td>
<td>Children and adults with mental illness, community</td>
<td>Psychotropic medications</td>
<td>Pharmacist</td>
<td>No</td>
<td>Pharmacist reviewed medication chart and electronic health record 1-3 months after psychiatrist appointment. Medication monitoring reviewed against best practice guidelines and potential for drug-drug interactions assessed using medication interaction database. Recommendations sent to prescriber.</td>
<td>American Psychiatric Association Practice Guidelines, Mount Sinai Conference Consensus recommendatio ns, Development Conference on Antipsychotic</td>
<td>1</td>
</tr>
<tr>
<td>Authors</td>
<td>Participants</td>
<td>Medication</td>
<td>Reviewer(s)</td>
<td>Involved parties</td>
<td>Monitoring standards</td>
<td>Drugs and Obesity and Diabetes guidelines used to define monitoring standards</td>
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<tr>
<td>Prentice &amp; Wright, 2014</td>
<td>Older adults, nursing home</td>
<td>Antipsychotic medications</td>
<td>Pharmacist</td>
<td>Care staff, Physician</td>
<td>Pharmacist reviewed symptoms, side-effects, and medication-related information, discussed with care staff, and made recommendations to physician.</td>
<td>NICE guidelines, standard data collection form to inform decision making</td>
<td></td>
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<tr>
<td>Gemelli et al., 2016</td>
<td>Older adults, nursing home</td>
<td>Sedative / hypnotic medications</td>
<td>Pharmacist</td>
<td>No</td>
<td>Pharmacist reviewed medication charts and where indicated made recommendations (dose reduction, medication discontinuation, re-evaluation of symptoms, or switch to alternative medication) to the prescriber.</td>
<td>-</td>
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<tr>
<td>Child et al., 2012</td>
<td>People with dementia, care home or community</td>
<td>Antipsychotic medications</td>
<td>Pharmacist</td>
<td>Yes – patient and family</td>
<td>Pharmacist reviewed medication chart and clinical records and discussed changes to antipsychotic prescribing with general practitioner, care staff, and patient (±family)</td>
<td>-</td>
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<tr>
<td>Johnson et al., 2012</td>
<td>Adults, community</td>
<td>Anti-depressant medications</td>
<td>Physician</td>
<td>Yes – patient</td>
<td>Physician completed face-to-face medication review</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Napolitano et al., 2012</td>
<td>Adults, community</td>
<td>Anti-depressant medications</td>
<td>Nurse</td>
<td>Yes – patient</td>
<td>Nurse prescriber completed face-to-face medication review including illness- and medication-related variables, patient understanding and beliefs, and risk assessment.</td>
<td>Patient Health Questionnaire Generalised Anxiety Disorder Scale</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Medications</td>
<td>Reviewer</td>
<td>Update?</td>
<td>Description</td>
<td>Scale</td>
<td>Score</td>
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<tr>
<td>Jordan et al., 2015</td>
<td>Elderly, nursing home</td>
<td>Psychotropic medications</td>
<td>Nurse</td>
<td>Yes – patient and family</td>
<td>Monthly nurse review according to a checklist incorporating psychotropic medication adverse effects other and unmet needs. Completed with patient and acting as a prompt to further activity, including prescriber medication review.</td>
<td>WWADR checklist</td>
<td>3</td>
</tr>
<tr>
<td>Patterson et al., 2010</td>
<td>Elderly, nursing home</td>
<td>Psychotropic medications</td>
<td>Pharmacist Physician</td>
<td>Yes – patient and family</td>
<td>Monthly pharmacists reviewed patient records, interviewed patients and family, to identify medication-related problems and used an algorithm to identify potentially inappropriate psychotropic medication prescribing. Pharmacist recommendations discussed with physician and medication decisions made.</td>
<td>Fleetwood algorithm for appropriateness of psychotropic drug prescription</td>
<td>3</td>
</tr>
<tr>
<td>Bach et al., 2017</td>
<td>People with dementia, nursing home</td>
<td>Antipsychotic medications</td>
<td>Pharmacist</td>
<td>No</td>
<td>Monthly pharmacist screened medication charts against criteria for appropriate antipsychotic use and made recommendations to the physician</td>
<td>Antipsychotic Use Survey Tool was used to determine appropriate and inappropriate antipsychotic prescribing</td>
<td>1</td>
</tr>
<tr>
<td>Morrison, 2009</td>
<td>Older adults, nursing home</td>
<td>Antipsychotic medications</td>
<td>General practitioner</td>
<td>NR</td>
<td>Six-monthly general practitioner completed structured review of</td>
<td>-</td>
<td>CD</td>
</tr>
<tr>
<td>Study</td>
<td>Population</td>
<td>Medications</td>
<td>Assessment</td>
<td>Decision Making</td>
<td>Team Meetings</td>
<td>Tool/Screen</td>
<td></td>
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<tr>
<td>Dahl et al., 2008</td>
<td>People with dementia, long-term care</td>
<td>Psychotropic</td>
<td>Nurse</td>
<td>Yes – family</td>
<td>Six-monthly multi-disciplinary team gather information using a standardized psychotropic assessment form covering symptoms, behaviour, side-effects, and patient/family concerns. Followed by a multi-disciplinary team meeting where recommendations to optimize prescribing are agreed and sent to the prescriber.</td>
<td>Psychotropic Assessment Tool</td>
<td></td>
</tr>
<tr>
<td>Branford, 1996</td>
<td>People with intellectual disability, institution</td>
<td>Psychotropic</td>
<td>Nurse</td>
<td>No</td>
<td>Regular multi-disciplinary meeting to review diagnosis, behaviour, and medication prescribing. Prescribing decisions made by consensus.</td>
<td>ABC PIMRA Reiss screen</td>
<td></td>
</tr>
<tr>
<td>Bisconer et al., 1995</td>
<td>People with intellectual disability, institution</td>
<td>Psychotropic</td>
<td>Physician</td>
<td>No</td>
<td>Six-monthly multi-disciplinary meetings to discuss presentation, medication side-effects, and broader treatment plan. Changes to prescribing made by consensus.</td>
<td>Standard report (no validated instruments)</td>
<td></td>
</tr>
<tr>
<td>Jauernig &amp; Hudson, 1995</td>
<td>People with intellectual disability, institution</td>
<td>Psychotropic</td>
<td>Pharmacist</td>
<td>No</td>
<td>Two-monthly multi-disciplinary meetings to discuss presentation and progress, review data collected on standardized forms, and agree medication recommendations to be made to treating physician.</td>
<td>Behaviour monitoring record forms Aberrant Behaviour Checklist Side-effect monitoring checklist</td>
<td></td>
</tr>
<tr>
<td>Study &amp; Year</td>
<td>Population</td>
<td>Medication Type</td>
<td>Professionals</td>
<td>Involves Family</td>
<td>Frequency</td>
<td>Review Involves</td>
<td>Other Considerations</td>
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<tr>
<td>Glaser &amp; Morreau, 1986</td>
<td>People with intellectual disability, institution</td>
<td>Antipsychotic medications</td>
<td>Physician, Nurse, Pharmacist, Psychologist, Care staff, Administrator</td>
<td>No</td>
<td>Monthly multi-disciplinary team review including indication for medication, symptoms, alternative treatments, and medication response. Recommendations made.</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Marcoux, 1985</td>
<td>People with intellectual disability, institution</td>
<td>Psychotropic medications</td>
<td>Physician, Psychologist, Nurse, Pharmacist</td>
<td>No</td>
<td>Three-monthly multi-disciplinary meetings to review symptoms, side-effects and other information and inform medication decisions.</td>
<td>Standard data sheets completed</td>
<td>2</td>
</tr>
<tr>
<td>Lepler et al., 1993</td>
<td>People with intellectual disability, community</td>
<td>Psychotropic medications</td>
<td>Nurse, Psychologist, Care staff, Physician, Yes – family or advocate</td>
<td>Yes – family or advocate</td>
<td>Three-monthly multi-disciplinary review of clinical presentation, medication response and side-effects, laboratory monitoring, alternative interventions, and other factors leading to medication recommendations based on team consensus. Final decisions are a combination of team recommendations, patient/family preference, and physician opinion.</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Ferguson et al., 1982</td>
<td>People with intellectual disability, institution</td>
<td>Antipsychotic medications</td>
<td>Physician, Psychologist, Social worker, Nurse, Pharmacist, Care staff</td>
<td>No</td>
<td>Monthly multi-disciplinary review of target symptoms and medication side-effects with data (counts of challenging behaviour) used to direct medication dose changes according to a specified protocol.</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Inoue, 1982</td>
<td>People with intellectual disability, institution</td>
<td>Psychotropic medications</td>
<td>Pharmacist, Physician, Nurse, Care staff</td>
<td>No</td>
<td>Monthly pharmacist collected data on patient condition, response to treatment, medication side-effects presented at multi-disciplinary meetings. Pharmacist recommendations for treatment discussed and accepted or declined.</td>
<td>Standard data forms used to inform reviews</td>
<td>2</td>
</tr>
<tr>
<td>Reference</td>
<td>Population</td>
<td>Treatment</td>
<td>Healthcare Professional</td>
<td>Monitoring</td>
<td>Description</td>
<td>Data Source</td>
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<tr>
<td>Ellenor &amp; Frisk, 1977</td>
<td>People with intellectual disability, institution</td>
<td>Psychotropic medications</td>
<td>Physician Pharmacist Nurse Psychologist Sociologist Therapist</td>
<td>No</td>
<td>Three-monthly pharmacist collected data on medication history, interactions, side-effects, clinical presentation, response to treatment, and made recommendations which were discussed and accepted or declined at multi-disciplinary meetings</td>
<td>Data collected on a standard form</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Electronic identification followed by clinician medication review (‘two stage’ medication review)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donat, 2006</td>
<td>People with mental illness, hospital</td>
<td>Psychotropic medications (PRN use)</td>
<td>Psychiatrist Psychologist</td>
<td>No</td>
<td>Automated identification of patients receiving PRN medication ≥3 times a week followed by case review by psychiatrist and psychologist using a semi-structured form to guide decisions. Further review by a senior management committee in some cases.</td>
<td>Local guidelines</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seltzer et al, 2000</td>
<td>Adults and children, community</td>
<td>Sedatives / hypnotic medication</td>
<td>Physician</td>
<td>NR</td>
<td>Automated identification of patients prescribed long-term or high-dose sedatives or intra-class polypharmacy followed by letter to prescriber to prompt review of medication. (This stage of medication review not well described)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Craig &amp; Mehta, 1984</td>
<td>Mental illness, hospital</td>
<td>Psychotropic medications</td>
<td>Physician</td>
<td>No</td>
<td>Automated identification of patients receiving high or low medication doses or polypharmacy followed by clinical review by two physicians to judge appropriateness of prescribing. Further review senior physicians where agreement not reached.</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Laska et al., 1980</td>
<td>People with mental illness, hospital</td>
<td>Psychotropic medications</td>
<td>Physician</td>
<td>No</td>
<td>Automated identification of patients receiving high or low medication doses or polypharmacy followed by medication review by two physicians and consultation with a peer-group, if necessary</td>
<td>-</td>
<td>2</td>
</tr>
</tbody>
</table>

Abbreviations: NR, not reported; CD, cannot determine; NICE, National Institute for Health and Care Excellence; WWADR, West Wales Adverse Drug Reaction; ABC, Aberrant Behaviour Checklist; PIMRA, Psychopathology Inventory for Mentally Retarded Adults

¹Review level categorised according to (Shaw et al., 2002)
Studies reported review of antipsychotic medications \((n=9\) studies), sedatives/hypnotics \((n=2\) studies), antidepressants \((n=2\) studies), or several psychotropic medication classes concomitantly \((n=13\) studies). A minority of reviews incorporated patient or family/advocate involvement.

Several studies report standardized methods of data collection that were used to inform medication review, although few used validated instruments to measure clinical variables. The majority of focused psychotropic medication reviews relied on implicit decision-making and clinician judgment, rather than explicit measures of medication appropriateness such as the Medication Appropriateness Index (Hanlon et al., 1992) or Beers Criteria (Beers et al., 1991).

### 4.3.3 Outcomes of focused psychotropic medication review

#### 4.3.3.1 Medication-related outcomes

A measure of change in psychotropic medication prescribing following focused psychotropic medication review was the most consistently reported medication-related outcome.

**4.3.3.1.1 RCTs**

Ballard et al, Jordan et al and Patterson et al all report a significant effect of focused psychotropic medication review in reducing psychotropic medication prescribing in cognitively-impaired elderly residents of nursing homes (pooled odds ratio \((OR) 0.24, 95\% CI 0.14\) to 0.39) (figure 4.3) (Ballard et al., 2015; Jordan et al., 2015; Patterson et al., 2010). Additional data obtained from the study by Moncrieff et al showed a non-
significant tendency to greater change in antipsychotic medication in adults with severe mental illness undergoing out-patient focused psychotropic medication review conducted by their usual psychiatrist than those receiving standard care (OR 0.38, 95%CI 0.12 to 1.19) but the direction of change in medication prescribing was not given (Moncrieff et al., 2016) (figure 4.4).

**Figure 4.3** Forest plot showing odds of reduction in psychotropic medication prescribing following focused medication review vs treatment as usual

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ballard et al</td>
<td>277</td>
<td>0.17 (0.05, 0.60)</td>
</tr>
<tr>
<td>Jordan et al</td>
<td>43</td>
<td>0.22 (0.06, 0.87)</td>
</tr>
<tr>
<td>Patterson et al</td>
<td>334</td>
<td>0.26 (0.14, 0.49)</td>
</tr>
<tr>
<td>Overall (I-squared = 0.0%, p = 0.831)</td>
<td></td>
<td>0.24 (0.14, 0.39)</td>
</tr>
</tbody>
</table>

*Plot size is determined by weight from random effects analysis
Abbreviations: OR, odds ratio; CI, confidence interval*
**Figure 4.4** Forest plot showing odds of *change* in antipsychotic medication prescribing following focused medication review vs treatment as usual

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>OR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moncrieff et al</td>
<td>60</td>
<td>0.38 (0.12, 1.19)</td>
</tr>
</tbody>
</table>

*Abbreviations: OR, odds ratio; CI, confidence interval*

4.3.3.1.2 Before-after studies

One-off focused psychotropic medication review was associated with an average of 34.0% (95%CI 32.9% to 35.2%) participants having change in medication prescription (Figure 4.5, data from 9 studies). Four before-after studies report the impact of focused medication review on antipsychotic medications prescribed for behavioural and psychological symptoms of dementia. These reviews, conducted by either a pharmacist or general practitioner, were associated with reduction or discontinuation of antipsychotic medications in between 20% and 61% participants.
Figure 4.5 Proportion of participants of included before-after studies with change in psychotropic medication prescription after one-off medication review

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in psychotropic medication</td>
<td></td>
</tr>
<tr>
<td>Johnson et al</td>
<td>2849</td>
</tr>
<tr>
<td>Napolitano</td>
<td>32</td>
</tr>
</tbody>
</table>

Reduction in psychotropic medication

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bach et al</td>
<td>20</td>
</tr>
<tr>
<td>Brantford</td>
<td>198</td>
</tr>
<tr>
<td>Child et al</td>
<td>70</td>
</tr>
<tr>
<td>Gemelli et al</td>
<td>34</td>
</tr>
<tr>
<td>Morrison et al</td>
<td>22</td>
</tr>
<tr>
<td>Prentice et al</td>
<td>3165</td>
</tr>
<tr>
<td>Seltzer et al</td>
<td>244</td>
</tr>
</tbody>
</table>

Average

Plot size is proportionate to participant number

Abbreviations: CI, confidence interval

Gemelli et al investigated pharmacist chart review of sedative/hypnotic medication in elderly people living in a nursing home (Gemelli et al., 2016). The intervention was associated with dose reduction or discontinuation in almost half (49%, n=19) of the sample by follow-up at three months.
Two before-after studies addressed the impact on medication prescribing of clinical review of long-term anti-depressant medication therapy in community-dwelling adults. One large Scottish study ($n=2,849$) found that over one-quarter (28.5%) of long-term (>2 years) anti-depressant users had medication change after in-person review by their general practitioner, with the majority of changes being medication discontinuation or dose reduction (Johnson et al., 2012). However, participants were not a random sample of those eligible as general practitioners were able to select patients who they believed would benefit most from a review and the results may over-estimate change in prescribing if this method were to be implemented more broadly. A similar study, conducted in England on a pilot scale ($n=32$), reported that medication change (increase, decrease, or cessation) followed just over half of the medication reviews conducted by a specialist nurse prescriber (Napolitano et al., 2012).

The four studies that used electronic prescribing records to identify prescribing that fell outside defined guidelines to generate alerts, prompting clinician focused psychotropic medication review, all report the process was associated with improved rates of guideline-compliant prescribing (Craig & Mehta, 1984; Donat, 2006; Laska et al., 1980; Seltzer et al., 2000).

Several studies report the association of a program of multi-disciplinary medication review with psychotropic prescribing (Bisconer et al., 1995; Branford, 1996; Ellenor & Frisk, 1977; Ferguson et al., 1982; Glaser & Morreau, 1986; Inoue, 1982; Jauernig
Most of these studies were conducted before 2000 and focused on the use of psychotropic medications for challenging behaviour in adults with intellectual disability, the majority of whom were receiving long-term institutional care. The quality of these studies is poor-fair, yet together they report results of psychotropic medication review of a relatively homogeneous group of over 1,000 people (adults, most with severe-profound intellectual disability and behaviour disturbance living in large institutional facilities), with follow-up of between 6 months and 4 years. Figure 4.6 shows the proportion of participants in these studies undergoing reduction or change in psychotropic medication following the review programs, where this metric is given or can be extrapolated from the published results. The average proportion changing prescription 57.6% (95%CI 53.2% to 62.0%). These studies demonstrate the association of focused psychotropic medication review with medication change in a potentially over-medicated group; most changes were dose reductions or discontinuations (although exact figures are often difficult to obtain from the published results).
**Figure 4.6** Proportion of participants of included before-after studies with change in psychotropic medication prescription after *medication review programme*

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in psychotropic medication</td>
<td></td>
</tr>
<tr>
<td>Bisconer et al</td>
<td>80</td>
</tr>
<tr>
<td>Glasser et al</td>
<td>28</td>
</tr>
<tr>
<td>Reduction in psychotropic medication</td>
<td></td>
</tr>
<tr>
<td>Ferguson et al</td>
<td>97</td>
</tr>
<tr>
<td>Inoue</td>
<td>251</td>
</tr>
<tr>
<td>Jauemig et al</td>
<td>25</td>
</tr>
<tr>
<td>Lepler et al</td>
<td>12</td>
</tr>
<tr>
<td>Average</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval

*Plot size proportionate to participant number*

Studies that do not report the proportion of participants with medication change still report an association with either reduction of overall psychotropic prescribing at group level or reduced rates of polypharmacy. Ellenor et al demonstrate a reduction of 37% in psychotropic prescription items over the course of a 2 year regular medication review (Ellenor & Frisk, 1977) and Marcoux et al found that their process of multi-disciplinary psychotropic medication review was associated with an average
dose reduction of 17% in those receiving antipsychotic medications (Marcoux, 1985). An exception to these findings is a more recent study by Dahl et al, who report the results of a thorough multi-disciplinary psychotropic review in people with dementia resident in nursing homes (Dahl et al., 2008). The review was associated with minimal change in prescribing of any class of psychotropic medication at aggregate level, although interpretation is limited by movement of participants into and out of the intervention group.

Psychotropic polypharmacy amongst participants before and after the medication review programme was reported by three studies. All report substantial reduction in total volume of psychotropics associated with focused psychotropic medication review (Bisconer et al., 1995; Ellenor & Frisk, 1977; Jauernig & Hudson, 1995).

4.3.3.2 Clinical and patient-related outcomes

A number of disparate clinical outcomes were measured in twelve studies (table 4.2). Ballard et al report significantly more neuropsychiatric symptoms (such as aggression, agitation, and psychosis) at nine-month follow-up in people with dementia receiving antipsychotic review compared with controls (group difference in Neuropsychiatric Inventory score 7.37, 95%CI 1.53 to 13.22) (Ballard et al., 2015). Furthermore, people receiving the intervention demonstrated a nominal worsening in health-related quality of life (measured with the DEMQOL-proxy) which did not reach statistical significance (group difference -4.54, 95%CI -9.26 to 0.19) (Ballard et al., 2017). The authors explain that because of a changed landscape of antipsychotic prescribing to those with dementia and the relatively low baseline rate of
antipsychotic medication use in the cohort, those prescribed an antipsychotic are likely to have the most severe neuropsychiatric symptoms. They postulate that this subgroup may benefit from antipsychotic use, and reductions following medication review can be deleterious. There was no difference in agitation, depression, or mortality between medication review and control groups.

The medication review intervention tested by Moncrieff et al was co-designed with people with severe mental illness with the aim of increasing patient involvement and agency in antipsychotic medication decision-making (Moncrieff et al., 2016). There was no difference in the Decision Self Efficacy Scale between those randomized to the intervention and those receiving treatment as usual, suggesting the focused psychotropic medication review did not improve patient’s confidence in discussions or decisions with the psychiatrist around psychotropic medication. Those in the review group demonstrated a tendency to greater medication adherence but no significant difference was found in other secondary outcome measures of patient satisfaction, attitude towards psychotropic medications, symptoms of psychosis, or side-effects of antipsychotic medications between groups at follow-up 2-4 weeks after the review meeting. However, implementation fidelity was poor and the study was not adequately powered to detect effect sizes.

Jordan et al reported more medication-related problems were identified and addressed with nurse-led psychotropic medication review than without (Jordan et al., 2015). There was no significant difference in change in dementia psychopathology or behaviour changes or functional ability between groups over the
study period and longer-term outcomes on patient health or well-being were not assessed.

Patterson et al measured the rate of falls in a high-dependency group with dementia (Patterson et al., 2010). The reductions observed in inappropriate psychotropic medication use in the intervention group over the control group did not translate to a difference in the rate of falls between groups (11.4 falls/100 person-months in control group vs. 16.3 falls/100 person-months in intervention group, \( p=0.09 \)), although the method of falls recording was subject to inaccuracies and authors note the study was underpowered.

Gallimore et al reviewed the potential for a pharmacist remote focused psychotropic medication review, conducted several weeks after out-patient psychiatry consultation, to improve rates of routine adverse medication event monitoring (Gallimore et al., 2016). The focused psychotropic medication review was associated with an increase in the proportion of participants with up-to-date laboratory monitoring and significantly reduced those at risk of drug-drug interaction but had no effect on the number of those who were monitored for movement side-effects. The actual benefit in terms of adverse medication event rates was not measured.

Bisconer et al was the only study to report rates of adverse medication events, albeit with a basic and unvalidated method (Bisconer et al., 1995). The proportion of the cohort with any physician-observed side-effect fell from 14% at baseline to 10% after
the review program, but the small number of participants \( n=80 \) is a limitation of this study.

Four studies report change in challenging behaviour as a result of antipsychotic review and reduction programmes in institutions for adults with intellectual disability (Bisconer et al., 1995; Ellenor & Frisk, 1977; Glaser & Morreau, 1986; Jauernig & Hudson, 1995). These studies report a decrease or no change in challenging behaviour associated with the delivery of the programme and the authors concluded that many psychotropic medications given in this population can be stopped without adverse behavioural effects. However, other work suggests that it can be problematic to reduce long-term antipsychotics used for behaviour in people with intellectual disability, with a substantial proportion suffering ill-effects (Sheehan & Hassiotis, 2017b).

**Table 4.2 Clinical outcomes of focused psychotropic medication review**

<table>
<thead>
<tr>
<th>Study reference</th>
<th>Clinical outcome</th>
<th>Measure</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RCTs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ballard et al., 2015</td>
<td>Neuropsychiatric symptoms</td>
<td>Neuropsychiatric Inventory (NPI)</td>
<td>Difference between intervention and control groups favours control 7.37 (95%CI 1.53 to 13.22, p=0.02)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Agitation</td>
<td>Cohen-Mansfield agitation inventory</td>
<td>Difference between intervention and control groups 4.60 (95%CI -1.43 to 10.63, p=0.13)</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>Cornell scale for depression in dementia</td>
<td>Difference between intervention and control groups -1.70 (95%CI -4.29 to 0.90, p=0.19)</td>
</tr>
<tr>
<td>Mortality</td>
<td>Death</td>
<td><strong>OR 0.67 (95%CI 0.39 to 1.14, p=0.15)</strong></td>
<td></td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------------------------------------</td>
<td>-----------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Ballard et al., 2017</td>
<td>Proxy health-related quality of life</td>
<td>DEMQOL-proxy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difference between intervention and control groups -4.54 (95%CI -9.26 to 0.19, p=0.06)</td>
<td></td>
</tr>
<tr>
<td>Moncrieff et al., 2016</td>
<td>Clinical symptoms of severe mental illness</td>
<td>Brief positive and negative side-effects scale (Brief-PANSS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difference between intervention and control groups 0.13 (95%CI -2.20 to 2.48)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Antipsychotic medication adverse side-effects</td>
<td>Liverpool University Neuroleptic Side-Effect Rating Scale (LUNSERS)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medication adherence</td>
<td>Medication Adherence Questionnaire (MAQ)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difference between intervention and control groups favours intervention -0.44 (95%CI -0.76 to -0.11)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Confidence in participating in clinical discussions and decisions</td>
<td>Decision Self-Efficacy Scale (DSES)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mean difference between intervention and control group -4.16 (95%CI -9.81 to 1.49)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient satisfaction</td>
<td>Client Satisfaction Questionnaire (CSQ-8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difference between intervention and control groups -0.29 (95%CI -3.04 to 2.45)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Attitude towards medication</td>
<td>Drug Attitude Inventory (DAI)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difference between intervention and control groups 1.65 (95%CI -0.09 to 3.40)</td>
<td></td>
</tr>
<tr>
<td>Jordan et al., 2015</td>
<td>Medication-related problems addressed (side-effects)</td>
<td>Frequency counts</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difference between intervention and control groups favours intervention 3.34 (95%CI 2.57 to 4.11, p=0.001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Functional ability</td>
<td>Bristol Activities of Daily Living Scale</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mean difference between intervention and control group 0.45 (95%CI -0.47 to 0.93, p=0.52)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dementia psychopathology</td>
<td>Manchester and Oxford Universities Scale for the Psychopathological Assessment of Dementia (MOUSEPAD)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Difference between intervention and control groups 4.67 (95%CI -0.04 to 2.78, p=0.06)</td>
<td></td>
</tr>
<tr>
<td>Patterson et al., 2010</td>
<td>Falls</td>
<td>Rate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>16.3 falls/100 person-months in intervention group vs. 11.4 falls/100</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Measure</td>
<td>Before</td>
</tr>
<tr>
<td>-------</td>
<td>--------</td>
<td>---------</td>
<td>--------</td>
</tr>
<tr>
<td>Gallimore et al., 2016</td>
<td>Up-to-date laboratory monitoring</td>
<td>Proportion of participants</td>
<td>54.1% (before); 72.1% (after)</td>
</tr>
<tr>
<td></td>
<td>At risk of drug-drug interaction</td>
<td>Proportion of participants</td>
<td>43.8% (before); 24.3% (after)</td>
</tr>
<tr>
<td></td>
<td>Movement side-effect monitoring</td>
<td>Proportion of participants</td>
<td>75.0% (before); 63.5% (after)</td>
</tr>
<tr>
<td>Branford, 1996</td>
<td>Clinical presentation</td>
<td>Subjective assessment</td>
<td>25% undergoing medication change had “good” outcome, 43% “poor” outcome (32% “unclear” outcome)</td>
</tr>
<tr>
<td>Jauernig &amp; Hudson, 1995</td>
<td>Challenging behaviour</td>
<td>Frequency counts</td>
<td>Average daily frequency of challenging behaviour lower after the intervention than at baseline in 80%</td>
</tr>
<tr>
<td>Bisconer et al., 1995</td>
<td>Challenging behaviour</td>
<td>Frequency counts</td>
<td>Mean decrease in challenging behaviour following intervention</td>
</tr>
<tr>
<td></td>
<td>Reported medication side-effects</td>
<td>Proportion of participants</td>
<td>n=11 (14%) before intervention, n=8 (10%) after intervention</td>
</tr>
<tr>
<td>Glaser &amp; Morreau, 1986</td>
<td>Aggressive challenging behaviour</td>
<td>Frequency counts</td>
<td>No significant difference between intervention and control groups¹</td>
</tr>
<tr>
<td>Inoue, 1982</td>
<td>Clinical presentation</td>
<td>Subjective assessment</td>
<td>“Positive change” in 96.5% receiving intervention, “negative” change in 3.5%</td>
</tr>
<tr>
<td>Ellenor &amp; Frisk, 1977</td>
<td>Challenging behaviour</td>
<td>Aberrant Behaviour Checklist (ABC)</td>
<td>“Slight increase” in challenging behaviour but no significant difference between intervention and control group¹</td>
</tr>
</tbody>
</table>

Abbreviations: OR, odds ratio; CI, confidence interval; RCT, randomised controlled trial
¹These studies had control groups only for secondary outcome of change in challenging behaviour
4.3.3.3 Economic outcomes

Five studies reported descriptive cost data in terms of savings made following focused psychotropic medication review but none conducted comprehensive economic evaluation (Ellenor & Frisk, 1977; Johnson et al., 2012; Jordan et al., 2015; Marcoux, 1985; Napolitano et al., 2012) (table 4.3). Interpretation of these data is constrained by the crude analyses used (potential savings from changes in medication were not offset against the costs of providing the medication review) and the age of some of the studies limits applicability to modern-day care.

Table 4.3 Economic outcomes of focused psychotropic medication review

<table>
<thead>
<tr>
<th>Study reference</th>
<th>Economic measure</th>
<th>Result</th>
<th>Author’s conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jordan et al., 2015</td>
<td>Direct cost of performing each medication review</td>
<td>Medication review cost was 31.50 USD (20.50 GBP, 28.20 EUR) (2015)</td>
<td>The nurse-led medication review was low cost and offers potential cost savings</td>
</tr>
<tr>
<td>Johnson et al., 2012</td>
<td>Reduction in medication prescribing costs following medication changes as a result of medication review</td>
<td>Reduced prescribing costs following the medication review with 2,849 people were estimated to be 23,320 GBP per year (2012)</td>
<td>Medication review provided reductions and prescribing and possible associated costs</td>
</tr>
<tr>
<td>Napolitano et al., 2012</td>
<td>Reduction in medication prescribing costs following medication changes as a result of medication review</td>
<td>Potential savings of 17,512 GBP over two years following medication reviews with 32 people (2012)</td>
<td>Savings can be made with timely and appropriate medication review</td>
</tr>
<tr>
<td>Marcoux, 1985</td>
<td>Reduction in medication prescribing costs following medication changes as a result of medication review</td>
<td>Estimated savings of 2,800 to 3,200 USD per month in prescribing costs following the review programme in 255 people (1985)</td>
<td>Medication review can result in savings</td>
</tr>
<tr>
<td>Eellenor &amp; Frisk, 1977</td>
<td>Reduction in medication prescribing costs following medication changes as a result of medication review</td>
<td>Net savings of 10,176 USD per year following 208 people receiving medication reviews (1977)</td>
<td>A reduction in medication expenditure can be achieved with medication review</td>
</tr>
</tbody>
</table>

Abbreviations: USD, United States Dollars; GBP, Great British Pounds; EUR, Euros
NB: Figures given as reported by study and not adjusted for inflation
4.4 Discussion

4.4.1 Principal findings

Psychotropic medication plays a central role in the treatment of mental disorders yet remains the subject of debate. Treatment benefits must be balanced against adverse medication events which are both common and distressing (Muench & Hamer, 2010). Rising rates of psychotropic prescription are observed worldwide, including in the UK (NHS Digital, 2019), despite the modest effect size of psychotropic medications for most indications (Seemüller et al., 2012) and the increasing evidence for non-pharmacologic interventions. From an economic perspective, psychotropic medications contribute a large proportion of the NHS total medication spend (Ewbank et al., 2018) which, when viewed in the context of non-adherence rates of up to 65% (Osterberg & Blaschke, 2005), accounts for significant healthcare resource waste. On a personal level, patient and carer views and preferences should be respected but many report feeling excluded and wish to play a greater role in psychotropic medication decisions (Morant et al., 2018). Medication optimisation aims to address these tensions through a variety of strategies, including medication review.

Pooled evidence from studies of medication review as a discrete intervention is inconclusive but, prior to the current work, there had not been a review of the literature about focused psychotropic medication review. The results of my systematic review show that focused psychotropic medication review has attracted ongoing interest and been instituted across different settings over the past four decades. There is considerable diversity in how focused psychotropic medication
review has been conceived and delivered, from one-off medication reviews conducted by a professional outside the usual clinical team, to a programme of meetings over months-years that are embedded in the person’s usual care.

Meta-analysis was possible on three of three RCTs included in this systematic review and demonstrated significantly greater likelihood of psychotropic medication reduction with focused psychotropic medication review than with treatment as usual in elderly nursing homes residents with dementia. Results from several uncontrolled before-after studies seem to support this finding by reporting an association between medication review and change (most often reduction) in medication prescribing, irrespective of participant group. This indicates the potential for improved prescribing following medication review but, although it seems logical that change in medication after a critical evaluation will be beneficial, the clinical gains following withdrawal of medication following focused psychotropic medication review cannot be assumed. It is also incorrect to assume that reductions in medication are the only desired outcome of medication review; in cases where medication is well-tolerated but providing sub-therapeutic effect it benefit, it may be most appropriate to increase the medication dose. Most studies did not measure benefits (or harms) associated with medication review; change in medication prescribing is an intermediary (or process) outcome which offers only a crude measure of medication optimization and only one study objectively assessed medication appropriateness against consensus guidelines (Patterson et al., 2010). One RCT reported identification of a greater number of adverse medication events as a result of focused psychotropic medication review, but not their mitigation or
resolution (Jordan et al., 2015). Two RCTs failed to demonstrate any benefit of medication review on clinically-meaningful parameters that were measured (Moncrieff et al., 2016; Patterson et al., 2010) and one RCT even reported deterioration in neuropsychiatric symptoms following medication review and subsequent reduction in medication prescribing (Ballard et al., 2017; Ballard et al., 2015).

The medication optimisation approach is intrinsically patient-centric (Royal Pharmaceutical Society, 2013) and medication review can provide an opportunity to explore patient beliefs and preferences and to reach shared treatment decisions. However, with one notable exception (Moncrieff et al., 2016), our review highlights a major lack of patient input and personalisation in existing focused psychotropic medication reviews. This represents a significant barrier to achieving shared decisions about medicine and true medication optimisation. The lack of patient involvement may reflect the age of several of the studies and a prevailing paternalism in medication decision-making in those prescribed psychotropic medications, especially if patients have cognitive impairments which affect mental capacity. However, this finding is not unique to psychotropic medication review. Willeboordse et al reviewed the literature related to any medication review and found that patient participation in the medication review process was infrequent. Where it did occur, it was limited to an exchange of information with the professional rather than representing a meaningful discussion and negotiation of treatment options (Willeboordse et al., 2014).
Potential for financial savings is a strong systems motivator for medication optimisation yet investigation of the economic implications and resource use of psychotropic medication review has largely been neglected. Any cost savings from reductions in prescribing and avoidance of adverse medication events must be offset against the initial outlay of performing medication review, additional activity generated (e.g. onward referrals or increased monitoring mandated by medication changes), and switches to more expensive medications or preparations. In these terms, my findings support calls for more attention to be paid to economic evaluation of medication review and other medication optimisation interventions (Faria et al., 2014).

In this thesis, I chose to review the evidence for focused psychotropic medication review as a means of medication optimisation in any population, with a view to gaining insights that could inform methods of psychotropic medication review in adults with intellectual disability. An alternative approach would have been to explore comprehensive medication review (i.e. medication review in which all of a person’s medicines are reviewed simultaneously) in people with intellectual disability only, thus narrowing the population whilst expanding the intervention under investigation. In fact, a systematic review along these lines has recently been published by researchers in the Netherlands who included eight studies in a review of the effectiveness of medication reviews in reducing medication related problems in people with intellectual disability (Nabhanizadeh et al., 2019). The medication reviews conducted differed in methodology and professional input, although all involved a multi-disciplinary team approach. Study quality was mixed, there were no
controlled trials, and several were limited by small sample sizes. Participants in all studies lived in residential institutions which limits the external validity of the findings. No quantitative synthesis was performed but the results showed that medication review was associated with reductions in the use of medication (either by number of prescribed medications or dose) and that medication review could identify medication-related problems. A smaller number of studies reported that medication-related problems were successfully reduced following the review. Consistent with the results of my review, no studies examined the impact of medication review on longer-term ‘downstream’ measures of health or wellbeing and economic evaluation of medication review interventions was missing. Thus, the overall findings of this review complement my own and the authors similarly conclude that medication review is a potentially-advantageous intervention but one that requires further research.

4.4.2 Limitations of the existing research

It is surprising that no medication review interventions included children and adolescents, given the public and professional concern that has been around rising rates of psychotropic use in this group (Sharma et al., 2016; Steinhausen, 2015).

The quality and reproducibility of future studies must be improved. Although recent studies that evaluate medication review interventions are more robust methodologically, the overall risk of bias in my findings is high, with limitations conferred by both study design and reporting.
Most studies were conducted without a control group and it is not possible to attribute changes in prescribing to the intervention. The short follow-up time or cross-sectional nature of many studies means that outcomes of medication review that may accrue over time (such as improvements in clinical indices) are not accounted for, nor is the possibility of reversal of changes in medication following the review. Many studies were retrospective evaluations, which introduces a potential source of bias in reporting and interpretation.

Data in the included studies were not sufficiently detailed to enable subgroup analysis of medication reviews, beyond grouping interventions by one-off medication review and ongoing review programs. Multi-disciplinary review programs, mostly conducted with participants with intellectual disability living in institutional care, tended to be associated with the greatest proportion of participants changing medication, although this could be a function of the pre-existing high level of psychotropic use in this group (Matson et al., 2000).

The findings do not suggest a professional discipline that should lead psychotropic medication review, although third-party reviews by a professional (usually a pharmacist) external to the usual team might be difficult to embed in routine care. As few as one-third of medication recommendations made by pharmacists are actioned by prescribers (Bach et al., 2017) and non-prescribers conducting reviews often report lacking influence (Maidment et al., 2016), highlighting the importance of good inter-professional communication and teamwork in complex medication review interventions (Chen & de Almeida Neto, 2007).
4.4.3 Strengths and limitations of the review

This is the first systematic review to synthesize the evidence for focused psychotropic medication review. I applied few limits to the search and included varied study designs in order to maximise the data I could use and the learning that was possible. I identified several additional articles through hand searches; this is likely to reflect the nebulous nature of the intervention and a lack of consistent terminology, as well as poor indexing of older studies. Another member of the research team independently appraised studies against pre-specified inclusion criteria and judged study quality using published frameworks. I conducted meta-analysis and calculated pooled effects where possible.

The deficits of the primary literature limit the strength of the conclusions it is possible to draw about the effects of psychotropic medication review. The majority of studies included were uncontrolled and prone to bias and confounding, and it is difficult to attribute causality in before-after designs. It is impossible to blind participants and practitioners to the intervention although blinding might not be essential where outcomes (e.g. prescribing rates) are objective. Clinical outcomes of medication review may only become apparent after some time and thus the limited follow-up in the included studies is a major problem. Diversity in outcome measures and reporting precluded more extensive meta-analysis. There is potential for publication bias to skew the results of this review and there were insufficient data to assess this risk statistically. I did not search the grey literature.
4.4.4 Future work

There are several ways in which the literature around medication review could be expanded and strengthened. Future trials should ensure standardized reporting of the intervention, for example, using the TIDieR (template for intervention description and replication) research checklist, so that interventions can be properly scrutinised and replicated. Use of a common core outcome set and the same measurement instruments in medication review evaluations would aid comparison between studies and the pooling of data to generate more powerful results (Beuscart et al., 2017; Silva et al., 2019). Moreover, inconsistencies in terminology should be resolved and the concept of medication review clearly defined and delineated from other attempts to optimise psychotropic prescribing (Zimmerman et al., 2017).

Research must also address the feasibility and acceptability of medication review interventions as their integration in routine care may be complex (Moncrieff et al., 2016; Ponniah et al., 2008) and they may not always be welcomed by patients or their carers (Petty et al., 2003; Uhl et al., 2018). Many of the medication reviews were led by community or hospital pharmacists though there is some evidence that people are less willing to discuss their medication with a pharmacist than a doctor (Jones et al., 1997) or are reluctant to accept pharmacist suggestions (Salter et al., 2007).

There is no universally-accepted standard procedure for medication review (Tarn et al., 2009). Although best-practice advice and consolidated tools have been developed to guide medication review and define potentially-inappropriate prescribing (Gallagher et al., 2008; Hanlon et al., 1992; Holt et al., 2010) few of the
medication reviews were informed by an empirically-derived model or best practice guidelines. There is the potential for electronic mechanisms, including e-prescribing, and the electronic patient record, to support medication review, in a way which does not yet seem to have been investigated fully (Lavan et al., 2016; Rose et al., 2017). I will discuss this potential further later in the thesis.

4.5 Conclusion

Focused psychotropic medication review as a structured and critical evaluation of a patient’s medication therapy has potential to contribute to medication optimisation. Despite much attention, the evidence for focused psychotropic medication review as a stand-alone intervention (or indeed, for any medication review in people with intellectual disability) is weak and it has not been shown that changes in prescribing associated with focused psychotropic medication review translate to improved clinical and patient-important outcomes.

Further high-quality research is essential before routine programmes of focused psychotropic medication review can be recommended, either in general or special populations such as people with intellectual disability. Standardisation of nomenclature, processes, and an agreed common outcome set that prioritizes patient-important measures is needed.

In the next chapter I will describe a study in which I assessed the feasibility of introducing a focused psychotropic medication review intervention to community
psychiatry of intellectual disability teams, in work that could inform the delivery of a later-stage efficacy trial.
Chapter 5: Feasibility study of the HealthTracker™-structured medication review in community psychiatry of intellectual disability teams

Note

A version of this work has been published as: Sheehan R, Strydom A, Marston L, Morant N, Foiri F, Santosh P, Hassiotis A. A structured medication review tool to promote psychotropic medication optimisation for adults with intellectual disability: feasibility study. BMJ Open 2019;9:e033827 (Appendix 20).

5.1 Introduction

The need for psychotropic medication optimisation in adults with intellectual disability was introduced in Chapter 1. To recap, the use of psychotropic medication (especially antipsychotic medications) is disproportionate to the level of recorded mental illness, people with intellectual disability are at greater risk of idiosyncratic reactions and adverse medication side-effects than their non-intellectual disabled counterparts, and are more likely to receive high psychotropic doses, polypharmacy, and to remain on psychotropic medication for extended periods (Bowring et al., 2017; De Kuijper et al., 2010; McGillivray & McCabe, 2006; Straetmans et al., 2007). Stimulated by high-profile scandals of abuse and recent epidemiological data, professional and patient and carer concern has converged on the topic and the imperative to improve practice has intensified.
Medication review has been proposed as a means of improving the use of prescribed medication and thus contributing to medication optimisation. Although evidence supporting psychotropic medication review as a standalone intervention is lacking, it has potential to improve the quality of medication use. Current medication review interventions are diverse with most published guidelines give generic advice only about how to structure and organise medication review (Clyne et al., 2008).

Few research studies have examined how clinicians conduct medication review in naturalistic settings. Tarn et al (2009) audio-recorded 100 encounters between 28 primary care physicians and older (>65 years) patients in the United States in which long-term medications were discussed, and analysed the data using content analysis. Physician approach to medication review varied considerably and the conversation about medication was frequently found to be sporadic and haphazard (Tarn et al., 2009). A systematic discussion of medication occurred in just over one-quarter of cases which, given the Hawthorne effect (in which people who are aware they are being observed alter their behaviour), may even have been an over-estimate compared with usual practice.

It may be the case that clinicians evaluate medication effects in a subtle way throughout consultations, while simultaneously assessing other aspects of the case, but lack of a dedicated and explicit discussion about medication might mean that important aspects are missed and the patient is not given the opportunity to declare their views. Such an approach explain why, in my qualitative work, several people with intellectual disability felt that medication was not spoken about at all during
their appointments. An uncoordinated approach may limit the clinical usefulness of
the review and account for some of the variation in the acceptability of medication
reviews to patients (Levenson et al., 2005).

In this chapter I will present the results of a feasibility study in which I explore the
potential use of a web-based structured psychotropic medication review method in
community psychiatry of intellectual disability teams in the UK.

5.1.1 HealthTracker™

HealthTracker™ is a web-based health monitoring platform that originated in the
NHS, and has since been spun-out as a commercial enterprise (https://www.healthtracker.co.uk/). My collaborator at King’s College London,
Professor Paramala Santosh, is a founder and director of the company. HealthTracker™ provides secure infrastructure on which confidential demographic
and health information can be added by clinicians, patients, or others who have been
given access rights. The nature of the data added, its manipulation, and display can
be configured according to the requirements of different projects. Thus, HealthTracker™ has been used to manage data in a number of research projects
(Absoud et al., 2011; Flamarique et al., 2016; Tuomainen et al., 2018) and is in routine
clinical use in the specialist Centre for Interventional Paediatric Psychopharmacology
and Rare Diseases clinic in the South London and Maudsley NHS Foundation Trust. It
has not previously been used in services for adults with intellectual disability.
5.1.1.1 HealthTracker™-Structured Medication Review (HT-SMR)

For the purposes of this study, the HealthTracker™ was configured to record basic demographic, clinical and treatment information (diagnosis, severity of illness, type of medication, dosage, duration of use), and the desired and undesired effects of medication. I have called this the HealthTracker™-structured medication review (HT-SMR). The content of the HT-SMR is represented in figure 5.1. The funding that was available for this project enabled me to select which of the basic components of the HealthTracker™ system would be included in the HT-SMR, but I was not able to change the content of the scales used, the nature of the output (the Modified Efficacy Index, see below), or to adapt the interface or the ‘look’ of the HealthTracker™ website. With additional time and/or funding, and subject to any licensing requirements, other elements and instruments are able to be added to the HealthTracker™, including, for example, medication adherence and compliance recording, more specific side-effect scales, or patient-completed questionnaires.

In this study, the Profile of Treatment Response (POTR) was used as a generic measure of psychotropic medication effect. The POTR is a clinician-completed scale that comprises two scales; one measuring therapeutic response to a medication over 11 symptom domains, and the other measuring potential adverse side-effects in 8 categories. Each item is rated by the psychiatrist conducting the medication review on a Likert scale using information gathered from observation and/or the clinical interview. Items that are not applicable can be marked as such, but incomplete reviews cannot be submitted to the system. Once a review has been completed, the information cannot be changed, thereby protecting the integrity of the data.
The items comprising the POTR were chosen and developed by a consensus exercise with mental health professionals as part of the initial development of the HealthTracker™ system (not part of this project). The items were selected to cover all major target symptoms and possible medication adverse side-effects. As part of this process, the content of the POTR was discussed and agreed with a consultation group of people with intellectual disability and carers (unpublished work).

Based on the responses to the therapeutic effect and adverse side-effect scales of the POTR, the HealthTracker™ imputes the Modified Efficacy Index (MEI) as the ratio between the benefit of a medication and the presence of adverse side-effects. The MEI is the ratio between the highest-rated therapeutic effect of the medication and the highest rated adverse effect (both rated on Likert scales). The output of the MEI is a score between 0.25 and 4.0. In general, a MEI score >1.5 suggests the medication is effective over time, under 1.5 suggests that the medication may be ineffective (Santosh et al, 2016), although these numbers must be interpreted with reference to the overall patient condition and in conjunction with their (and family or carer) views.

The MEI is displayed in a simple color-coded matrix that allows viewers to see how the patient has responded to treatment. The matrix includes green, white, and red zones, loosely corresponding with ‘overall benefit’, ‘trade-off between benefit and adverse side-effects’, and ‘overall predominance of adverse side-effects’. It should be noted, however, that the MEI is calculated purely on the basis of information
provided by the clinician and acts only as a guide to decision-making. It does not alter clinical responsibility.

The HealthTracker™ system of medication review (including the POTR and MEI) have been formally tested in two studies. In the first of these studies, the system was demonstrated to be effective in capturing variations in the efficacy of aripiprazole treatment longitudinally at individual and group levels (Santosh et al, 2017). In the second study, the usefulness of the POTR was tested in 50 children and adolescents attending a specialist psychiatric clinic for autism; the study concluded that the POTR was useful clinically and helped to identify treatment response at the patient level, thus assisting clinicians in decision-making regarding optimal prescribing (Lanzarini, 2018).

The Clinical Global Impression-Improvement (CGI-I) is also completed by the psychiatrist for each medication as a further measure of medication effect. The CGI-I is a well-established rating tool that can be completed quickly and easily in clinical settings to track response to interventions and to quantify patient progress (Busner & Targum, 2007).

The HT-SMR can be used once, as a cross-sectional review, or more than once across different time points, in which case a longitudinal profile of treatment response is created, with the function to visualise this graphically.
Figure 5.1 HealthTracker™-structured medication review

HealthTracker™– based Structured Medication Review (intuitive, interactive, web-based, password protected)

Profile Of Treatment Response (POTR)

- Clinical Information
  (age, gender, ethnicity, diagnoses)
- Treatment Information
  (start and end date of treatment, daily dose, presence of non-pharmacological interventions)
- Psychotropic-induced Symptom Change
  (improvement, no change, worsening)
- Psychotropic Side Effects
- Pre-Medication Clinical Global Impression - Severity (CGI-S)
- Post-Medication Clinical Global Impression – Severity (CGI-S) & Post-Medication Clinical Global Impression – Improvement (CGI-I)

Imputed Modified Efficacy Index
(helps busy clinicians by using internal algorithms to impute the Efficacy Index)

HealthTracker™-based POTR Imputed Modified Efficacy Index Report
(visual presentation of Imputed Modified Efficacy Index, including for previously used medications to assist clinicians in making a decision about Medication)

Longitudinal POTR Clinical Report
(clinicians can identify most effective medication for specific symptoms, and side-effects produced by them)
5.1.2 Complex interventions

A complex intervention is defined as one that has a number of components (Craig et al., 2008). An intervention can be made complex by virtue of: the number of interacting components; the number or difficulty of behaviours required by those delivering or receiving the intervention; the number or variability of outcomes; or the degree of flexibility or tailoring of the intervention permitted; or a combination of any of the above.

Medication review may be considered a complex intervention for a number of reasons. The target of the intervention, prescribing behaviour, arises secondary to a dynamic decision-making process and is subject to multiple influences both internal and external to the psychiatrist including cognitive and emotional aspects, marketing efforts, patient characteristics, and contextual factors (Murshid & Mohaidin, 2017). The setting within which medication review is completed is varies significantly; psychiatric consultations, especially in adults with intellectual disability, may be conducted in different ways, using different methods of communication, and with different stakeholders present, thus demanding a degree of flexibility in how a formalised intervention is interpreted and used. Finally, that the HT-SMR is an online tool introduces potential practical difficulties, even in modern clinical settings.

5.1.3 Logic model for the Health Tracker™-Structured Medication Review

A logic model is a diagrammatic representation on the theory underlying an intervention (Kellogg Foundation, 2004). Logic models describe assumptions regarding the cause of a problem, the intended activities forming the intervention,
and the anticipated short-, medium- and long-term outcomes (Moore et al., 2015). Logic models can be built using academic theory, experience, ‘common sense’, or a mix of these approaches (Pawson & Tilley, 1997). The logic model underpinning the HT-SMR is presented in figure 5.2 and the rationale explained in prose in the following paragraph.
Figure 5.2 Logic model for the HealthTracker™-structured medication review

Abbreviations: HT-SMR, HealthTracker™-structured medication review; STOMP, Stopping The Over-Medication of People with learning disabilities; IT, information technology
The HT-SMR presents a practical and scalable intervention in the pursuit of medication optimisation that is used at the individual patient level. A lack of systematic treatment evaluation has been identified as a reason for poor adherence to clinical guidelines for prescribing of psychotropic medications to people with intellectual disability (Ramerman et al., 2017). Using the HT-SMR creates a dedicated space in the psychiatric appointment for the discussion of psychotropic medication and its effects. The HT-SMR allows for flexibility in how information is gathered whilst ensuring that the medication evaluation is comprehensive as all common medication effects are covered. The HT-SMR incorporates the use of simple rating scales; the summation and graphical representation of data gathered therein could function as a rudimentary form of clinician decision support, as well as acting as a visual adjunct and a springboard for discussion with the patient and/or carer. Standardised documentation provides a record of the review that is easy to interpret and compare against across time and between clinicians, reducing the inertia and the status quo bias that can result in long durations of (sometimes unnecessary) treatment. It is a method that does not create excessive disruption to the current methods of working, that is, it is incorporated in routine appointments, does not require additional staff, dedicated clinics, or specialist equipment, all of which could make implementation difficult. Together, these potential benefits of HT-SMR may contribute to medication optimisation, including enhanced patient and carer involvement in the medication review process.
5.1.4 The rationale for a feasibility study

Feasibility, or pilot, studies are a key component in the process of developing and evaluating complex interventions that is used to determine whether the intervention is appropriate for further testing (Craig et al., 2008). This can avoid the time and expense of conducting a definitive trial only for it to be undermined by problems of recruitment, retention, acceptability or compliance (Eldridge et al., 2004). The focus of a feasibility study is on testing the methods and processes that might be employed in a future efficacy study, and identifying adaptations that might be needed in order for a full-scale study to run smoothly and successfully (Bowen et al., 2009). Thus, objectives of a feasibility study might be to: investigate recruitment methods and recruitment potential; trial data collection procedures and test the use of outcome measures; determine the acceptability of an intervention and study procedures; and estimate resources needed to conduct the study (Ormond & Cohn, 2015). A preliminary evaluation of the effect of an intervention can sometimes be made as part of a feasibility study, although studies are not powered to provide definitive results and hypothesis testing should not be considered a core aim of the feasibility study (Leon et al., 2011).

The terminology of feasibility and pilot studies are often used interchangeably and there is a lack of consensus in the precise meaning of each term (Blatch-Jones et al., 2018). The National Institute for Health Research has attempted to distinguish feasibility studies, which answer the question “can this study be done?” from pilot studies, which are smaller-scale versions of the main study (National institute for
Health Research, n.d.). Pilot studies may include control groups and randomisation, whereas these features are less likely in feasibility studies (Whitehead et al., 2014).

5.1.5 Aims
The aim of the work in this chapter is to investigate the feasibility of evaluating outcomes of the HT-SMR in a full-scale clinical trial in community psychiatry of intellectual disability teams.

Specific objectives were to test the recruitment strategy and estimate rates of recruitment of clinicians and people with intellectual disability, to assess uptake of the intervention in real-world clinical settings, and to gather feedback that could inform future development and refinement of the HT-SMR.

5.2 Methods
5.2.1 Study procedures
This was a single-arm feasibility study conducted over a six-month period in five community psychiatry of intellectual disability services in London, UK. All services were part of the NHS.

The study and its rationale were presented to psychiatrists in participating clinical teams, and they were then invited to take part in the study. If they agreed, they were given a unique password to access to the HealthTracker™ website hosting the structured medication review (SMR) for the study period. I trained psychiatrists on using the HT-SMR in face-to-face small-group sessions focused on the practicalities
of opening a case and entering data, and used a fictional patient to reinforce the learning. I was available throughout the study for support by phone, e-mail, or in-person, as needed.

Adults (>18 years) with intellectual disability were eligible to take part in the study if they were under the care of a participating clinical team and were prescribed psychotropic medication of any type and for any indication. Psychiatrists were asked to briefly introduce the research to potential participants and/or their carers, either at routine appointments or by sending a short information leaflet through the post (Appendix 21). The contact details of people with intellectual disability who expressed interest were passed to me and I then met with them (and their carer, where appropriate) to explain the research in more detail and confirm eligibility (Appendices 22-23). Written informed consent was obtained from all people with intellectual disability; this covered the use of HT-SMR in future appointments (as an addition to standard clinical care) and for use of their data for research purposes (Appendices 24-25). Ability to consent to take part was assessed according to the principles of the Mental Capacity Act (Department of Health, 2005). If a person lacked capacity to consent, a family member or nominated consultee (such as a staff member who was not directly involved in the study) was sought to give advice to the research team on the person’s inclusion (British Psychological Society, 2008). It was made clear that all personal data would be handled securely and used only for the purposes of this study, and that the participant could withdraw at any time. All study materials were available in accessible format.
When a participant was recruited to the study, their psychiatrist was informed and they were then able to use the HT-SMR in appointments with that person. Participants with intellectual disability (or their carers) were not contacted again by the research team after having given consent.

5.2.2 Data management and analysis

Each participant with intellectual disability was assigned a unique identification number when they were registered with the HealthTracker™ system. Thus, the data collected in the medication review were pseudonymised and as a researcher, I was not able to link the results of a medication review to a specific individual. The data were stored on a secure electronic cloud.

At the end of the study period, data from medication reviews were downloaded from the HealthTracker™ as a comma-separated values (CSV) file into SPSS v.24 (IBM Corp. 2016. SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp). For data security, these data were stored on the UCL Data Safe Haven and backed-up on a password-protected encrypted external hard drive. The POTR, MEI and CGI-I results were summarised with descriptive statistics. Spearman’s correlation between the MEI and CGI-I and the psychiatrist’s decision to change or not change medication were calculated. Owing to the skewness of the data, non-parametric tests were used to test the significance of associations.
5.2.3 Feasibility measures

I gauged interest from clinical teams and individual psychiatrists to take part in the study and recorded the rates of referral and recruitment of people with intellectual disability, and of uptake of the medication review tool in routine clinic appointments. Reasons for not recruiting people who were referred to the research team were noted. As this was a feasibility study, a formal sample size calculation was not performed but my rough *a priori* estimate was that up to 25 psychiatrists and 100 people with intellectual disability would be recruited in total, based on previous feasibility studies that have trialled similar interventions in community settings (Moncrieff et al., 2016; Mukadam et al., 2018) and I believed would enable assessment of referral, recruitment, completion of the HT-SMR, and sufficient feedback to inform a later full-scale trial.

5.2.4 Participant characteristics

Characteristics of adults with intellectual disability who were recruited and descriptive data concerning diagnosis and medication use are reported. Medication doses were converted to defined daily dose (DDD) (World Health Organisation, n.d.).

5.2.5 Acceptability and implementation

At the end of each medication review, psychiatrists asked people with intellectual disability, “How able were you to say everything you wanted to say about medication today?” Answers were scored on a five-point Likert scale with pictorial cues alongside the response set to improve understanding (Appendix 26).
At the end of the study period, psychiatrists were invited to complete an anonymous web-based survey, hosted on UCL Opinio, which was designed for this study with a mix of closed and open-ended questions (Appendix 27). The survey concerned the research process, experience and views on use of the online review system, and suggested adaptations to maximise usability and utility of the medication review in its future development. Responses to the psychiatrist feedback questionnaire were summarised in a structured analysis within pre-determined categories. All data from this were managed in SPSS v.24 and Microsoft Excel.

5.2.6 Ethical approval

I obtained research ethics approval for this study from the London Bridge NHS Research Ethics Committee (ref: 18/LO/1112) (Appendix 28). Local Research and Development approvals at each participating NHS Trust were obtained before any research activities were conducted.

5.3 Results

5.3.1 Recruitment and uptake

Five community intellectual disability teams and fifteen psychiatrists were invited and agreed to take part in the feasibility study which was conducted between September 2018 and March 2019. Eight psychiatrists were of consultant grade (5 male and 3 female) and seven psychiatrists were trainees (2 male and 5 female, with between 6 months and 3 years’ experience working in with people with intellectual disability). Together, 94 people with intellectual disability were referred as potential participants over the six-month study period and 79 (84%) of these were recruited to
the study. Thirty-nine (49%) participants gave consent and a consultee gave advice about inclusion in the remainder of participants.

Psychiatrists used the online system for medication review in 68 people (86% of those recruited). A number of people (n=21) had more than one medication review (when either more than one medication was reviewed at a single time point, or a single medication was reviewed on more than one occasion) giving a total of 97 discrete HT-SMRs completed during the study period. The study flow diagram is shown in figure 5.3.
Figure 5.3 Participant flow through feasibility study

Potential participants identified

$n=94$

Not recruited

$n=15$
Not eligible ($n=2$)
Declined to participate ($n=3$)
Not contactable ($n=3$)
Did not attend meeting ($n=2$)
Unable to identify consultee ($n=5$)

Participants recruited

$n=79$

HT-SMR not completed

$n=11$
Participant did not attend appointment
Clinician chose not to use HT-SMR

HT-SMR completed

$n=68$

Medication treatment episodes reviewed

$n=97$
There was a steady state of referral, recruitment and review tool use (figure 5.4). Recruitment and uptake of the HT-SMR was unequal between participating community intellectual disability teams and not related to the number of psychiatrists in each of these teams (figure 5.5). Each psychiatrist conducted a median of 7 medication reviews using the HT-SMR (range 0-20). No harms or unintended consequences were reported during the study and no participants withdrew their consent.

**Figure 5.4** Rate of referral, recruitment, and use of the HealthTracker™-structured medication review over the study period
5.3.2 Participant information and data from medication reviews

Demographic data of participants with intellectual disability who had medication review are summarised in table 5.1. The group was relatively young and the majority were reported to have mild intellectual disability. A primary diagnosis was not recorded in just over half of the participants; in these cases it is possible that psychotropic medication was prescribed for challenging behaviour.
Table 5.1 Demographic characteristics of participants with intellectual disability who underwent HealthTracker™-structured medication review

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<th>Characteristic</th>
<th>n (%)</th>
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<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>41 (60%)</td>
</tr>
<tr>
<td>Female</td>
<td>27 (40%)</td>
</tr>
<tr>
<td><strong>Age at first HT-SMR, years</strong></td>
<td></td>
</tr>
<tr>
<td>18-25</td>
<td>23 (34%)</td>
</tr>
<tr>
<td>26-35</td>
<td>16 (24%)</td>
</tr>
<tr>
<td>36-45</td>
<td>8 (12%)</td>
</tr>
<tr>
<td>46-55</td>
<td>17 (25%)</td>
</tr>
<tr>
<td>55-65</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>&gt;65</td>
<td>3 (4%)</td>
</tr>
<tr>
<td><strong>Degree of intellectual disability</strong></td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>42 (62%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>18 (26%)</td>
</tr>
<tr>
<td>Severe-profound</td>
<td>8 (12%)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>35 (51%)</td>
</tr>
<tr>
<td>Black</td>
<td>14 (21%)</td>
</tr>
<tr>
<td>Asian</td>
<td>10 (15%)</td>
</tr>
<tr>
<td>Mixed / other</td>
<td>7 (10%)</td>
</tr>
<tr>
<td>Not known / not given</td>
<td>2 (3%)</td>
</tr>
<tr>
<td><strong>Primary diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Schizophrenia spectrum disorder</td>
<td>12 (18%)</td>
</tr>
<tr>
<td>Mood disorder</td>
<td>5 (7%)</td>
</tr>
<tr>
<td>Anxiety disorder</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Personality disorder</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Pervasive developmental disorder</td>
<td>7 (10%)</td>
</tr>
<tr>
<td>Attention deficit hyperactivity disorder</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Missing</td>
<td>37 (54%)</td>
</tr>
</tbody>
</table>

*Abbreviations: HT-SMR, HealthTracker™-structured medication review*
Of the 97 HT-SMRs conducted using the system, the most commonly reviewed medication class was antipsychotics (49 reviews), followed by anti-depressants (28 reviews) (table 5.2). The median prescribed dose of medication reviewed was 100% DDD (inter-quartile range, IQR, 50-133%) and median duration of use was 18 months (IQR, 5-56 months). Following the HT-SMR, psychiatrists advised a change to medication in just over one-third \( (n=27, 36\%) \) cases.
Table 5.2 Summary results from the HealthTracker™-structured medication reviews completed (n=97 reviews)

<table>
<thead>
<tr>
<th>Medication class reviewed</th>
<th>Number of reviews (% of all reviews)</th>
<th>Median DDD of medication reviewed (IQR)</th>
<th>Median duration of use, months (IQR)</th>
<th>Median Modified Efficacy Index (IQR)</th>
<th>Median CGI-Improvement (IQR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antipsychotic</td>
<td>49 (51%)</td>
<td>67 (45-100)</td>
<td>24 (4-60)</td>
<td>2.0 (1.0-3.0)</td>
<td>1.5 (1.0-2.0)</td>
</tr>
<tr>
<td>Anti-depressant</td>
<td>28 (29%)</td>
<td>150 (87-200)</td>
<td>12 (4-24)</td>
<td>2.0 (1.4-3.0)</td>
<td>2.0 (1.0-3.0)</td>
</tr>
<tr>
<td>Anxiolytic / sedative</td>
<td>9 (9%)</td>
<td>24 (2-54)</td>
<td>100 (39-100)</td>
<td>3.0 (2.3-4.0)</td>
<td>3.0 (2.0-3.0)</td>
</tr>
<tr>
<td>Medication for ADHD</td>
<td>9 (9%)</td>
<td>120 (78-138)</td>
<td>18 (12-78)</td>
<td>2.0 (1.0-4.0)</td>
<td>2.0 (1.0-2.5)</td>
</tr>
<tr>
<td>Mood stabiliser</td>
<td>2 (2%)</td>
<td>33</td>
<td>96</td>
<td>1.2</td>
<td>2.5</td>
</tr>
<tr>
<td>All</td>
<td>97 (100%)</td>
<td>100 (50-133)</td>
<td>18 (5-56)</td>
<td>1.5 (1.0-3.0)</td>
<td>2.0 (1.0-3.0)</td>
</tr>
</tbody>
</table>

Abbreviations: DDD, defined daily dose; IQR, inter-quartile range

1 Modified Efficacy Index is the ratio between the score in the domain with the greatest therapeutic benefit to the score in the domain with the worst rated adverse side-effect. Higher scores indicate more favourable medication response.

2 CGI is scored between 1 (very much improved) and 7 (very much worse)
The HealthTracker™ Modified Efficacy Index (MEI) can take a value of 0.33 to 4.0, where higher values equate to a more favourable therapeutic effect:adverse side-effect ratio. The median HealthTracker™ imputed MEI for medications reviewed was 1.5 (IQR 1.0-3.0).

The CGI-I is scored such that lower scores indicate a greater degree of clinician-rated improvement. The median CGI-I for all medications was 2.0, consistent with a clinician rating of ‘much improved’ with medication. There was a statistically-significant negative correlation between the MEI and the CGI-I ($\rho = -0.296$, $p=0.024$; indicating ‘fair’ correlation between the two measures (Chan, 2003) (figure 5.6).
The MEI was significantly lower (i.e. a less favourable medication response) in those in whom a medication change made following the review (median MEI 1.0, IQR 0.67-2.0) compared with those in whom no medication change was made following the review (median MEI 1.5, IQR 1.3-3.0) \((p=0.011)\) (figure 5.7).
5.3.3 Acceptability and implementation

When asked “How able were you to say everything you wanted to say about medication today?”, participants with intellectual disability responded “very easy” or “easy” in 54 (70%) cases, “not easy or difficult” in 14 (18%) cases, “difficult” or “very difficult” in 1 (1%) case. The question was not answered by 9 (12%) participants with intellectual disability.

Fourteen psychiatrists out of fifteen completed the online feedback questionnaire. Results are presented as major themes with anonymised quotations to illustrate points of interest.
5.3.3.1 Feedback about the recruitment process

Although the majority (13/14) of psychiatrists reported that it had been ‘easy’ to introduce the study to potential participants, most (11/14) had also encountered barriers. The main barriers to recruitment were “time constraints” within appointments and difficulties explaining the research to potential participants, especially those with more severe intellectual disability.

Psychiatrists were asked if the people who did not wish to hear more about the research had given reasons for their decision. The most commonly reported reason (8 cases) was worry about the commitment or inconvenience the research would entail. Others declined to hear more as they were already taking part in research or were content with their current medication regimen and did not want to discuss this further. Seven psychiatrists reported that the some carers had not wished to pursue the research opportunity, either because they felt it was not appropriate or because they were not willing to act as a consultee in cases where the person with intellectual disability was likely to lack capacity to provide informed consent.

5.3.3.2 Ease of using the HealthTracker™ online system

Twelve psychiatrists reported having used the online system for medication review. In response to the question, “How easy was it to use the HealthTracker?” only one person reported it was “difficult”; the majority said it was “easy” or “very easy.”
5.3.3.3 Benefits of HT-SMR

Eight out of 12 psychiatrists were of the opinion that using the online medication review had helped people with intellectual disability or their carer to be more involved in the discussion about medication. Psychiatrists commented that it had been “helpful as a template” in “framing the discussion around medication” and that its use facilitated “more in-depth,” “comprehensive” or “collaborative” medication review. The transparency of medication review using the system was described as an advantage: “[using the tool] was an eye-opener for the patient and carer. They could hear the specific questions being asked systematically and seeing the matrix [the graphical representation of the MEI] was really useful, particularly for a few participants who were not clear about medication”.

5.3.3.4 Disadvantages of the HT-SMR

Six psychiatrists described logistical problems in using a system which required internet connectivity e.g. computers not working or running fast enough, lack of internet access in clinic settings, not having portable devices for domiciliary visits. Using the system was reported to have taken additional time which was sometimes difficult to find in the space of a regular appointment.

Just over half (7/12) of the psychiatrists expressed the view that using the online medication review had interfered with their interaction with the patient or carer with one remarking that they had spent “more time focussed on the computer rather than face-to-face personal interaction”. Two psychiatrists considered the system too rigid
and resisted the “imposed structure” of the medication review which they believed was not always aligned with the patient’s most pressing concerns.

5.3.3.5 Effect on decision-making

Eight out of 12 psychiatrists thought that undertaking the HT-SMR had helped them to make a decision about medication and 5/12 considered the tool made it more likely they would change medication compared with their usual practice. However in the survey free-text responses most commented that the medication review did not cause them to change decisions they would ordinarily have made, rather, the HT-SMR was viewed as “an additional tool” which could “confirm a clinical impression,” “justify decisions” and give clinicians “more confidence” in their actions.

5.3.3.6 Adaptations and views about future use

Eight out of 12 psychiatrists thought that SMR should be used more widely. Suggestions to improve the system centred on making the system more “user friendly” and “intuitive” for psychiatrists, and integrated with the existing electronic health record, rather than existing as a separate system. Three psychiatrists also mentioned improving the accessibility for people with intellectual disability and incorporating their views more formally in the medication review, for example, by “adding a weight to the [decision-support] algorithm based on patient preference”.
5.4 Discussion

5.4.1 Main findings

There is a need to improve the quality of psychotropic medication use in people with intellectual disability yet despite expert guidelines of good practice (Royal College of Psychiatrists, 2016; Shankar et al., 2019) there has been relatively little work to investigate practical methods to achieve medication optimisation in this group. The current study introduced a structured medication review tool, the HT-SMR, in community psychiatric services for adults with intellectual disability and demonstrates that it would be feasible to test outcomes of this approach in a definitive clinical trial. However, a further period of refinement of the HT-SMR would be of benefit in order to strengthen the patient (and carer) role in the review process and improve integration with existing systems.

Perhaps owing to the scrutiny currently applied to psychotropic prescribing and the need for clinicians to be seen as being proactive in responding to this, clinical teams and psychiatrists that I approached were keen to take part in this research. Including people with intellectual disability to research can be challenging for various reasons (Mulhall et al., 2018) but the number of participants we recruited was satisfactory, close to my original broad expectation, and the referral:recruitment ratio was high, indicating the processes of participant identification, recruitment and consent were appropriate. People are more likely to take part in research when the first approach is made by a trusted clinician (Peckham et al., 2018), although this can also place clinicians in the role of ‘gatekeeper’, and some may only suggest the research to those that they deem suitable (Fletcher et al., 2012). It also introduces an extra step
in the recruitment process and the method was time-intensive as it often involved me contacting people outside their appointment times and visiting them individually at their home.

A relatively high proportion of potential participants with intellectual disability were judged not to have capacity to consent to take part in the research and in these cases a consultee was requested to give advice on the person’s inclusion, in accordance with the Mental Capacity Act (Department of Health, 2005). Acting through intermediaries can present additional obstacles to research which need to be considered in the design of trials including people with intellectual disability (Nicholson et al., 2013). I found that a significant number of people, particularly paid carers, were hesitant to act as a consultee. This is perhaps because they did not fully understand the implications of the request, because they deemed themselves unqualified for this role, or because they did not feel confident in signing a quasi-legal document.

A key question in this feasibility study was whether psychiatrists were able and willing to integrate use of the HT-SMR into their standard practice, given the demands on their time and numerous mandated clinical and administrative tasks (Torrey & Drake, 2010). Uptake of the HT-SMR was good, though not universal; three psychiatrists did not use the tool at all and eleven people with intellectual disability who were recruited did not have a HT-SMR. The reasons for these, apparently willing, psychiatrists not engaging with the HT-SMR at all are not entirely clear; it would be
useful in future work to explore in more depth specific barriers these clinicians encountered.

One of the limitations of this study (also discussed below) is that I was not able to calculate the rate of HT-SMR use in those recruited as I lacked the number of potential appointments in which it could have been used. Missed appointments are one likely cause that limited the HT-SMR during the study period; the rate of missed appointments is higher in psychiatric clinics than in other medical specialties (Mitchell & Selmes, 2007), and may be higher still in intellectual disability services. There are likely other reasons too, including psychiatrist factors (e.g. the psychiatrist deciding not to complete the review, not having time, or not being able to complete the tool) and patient factors (e.g. not wishing to speak about medication during that appointment).

One of the main advantages of using the HT-SMR might be the application of structure to medication reviews which may otherwise be prone to disorganisation and risk missing important patient concerns. There is little evidence as to how psychotropic medication is reviewed in current clinical practice in the UK, although the authors of the most recent antipsychotic use in intellectual disability audit completed as part of the Prescribing Observatory for Mental Health (POMH-UK) programme highlighted deficiencies in monitoring and recording of adverse side-effects (Paton et al., 2016). Routine outcome monitoring using standardised instruments is recommended (Royal College of Psychiatrists, 2016) but rarely practised by psychiatrists (Tasma et al., 2018). Another major advantage of the HT-
SMR is that it stores comprehensive medication-related information in a standardised way which is easily interpreted. This offers a means of maintaining a degree of continuity, established as being important for SDM approaches to be viable, even where continuity in clinician or paid care staff may be lost.

The HealthTracker™ imputed MEI is a potential future outcome measure that could be used in a clinical trial. In a trial, we would wish to see if MEI changed over time with sequential reviews, that is, the MEI should increase over time, indicating an improving risk:benefit ratio. The MEI was correlated with the overall CGI-I (a valid and reliable measure of treatment effect) and was lower in those in whom medication changes were made compared with those in whom medication remained unchanged. Both of these results were expected and provide some validity for using this approach. However, there may also be disadvantages to using a single measure of medication effect, particularly in those who receive polypharmacy, as psychiatrists (and patients and their carers) may find it difficult to attribute changes to a specific medication. One psychiatrist in feedback suggested the MEI was a crude measure that could be ‘gamed’ by the clinician and a future trial would need to incorporate other measures that address the multi-dimensional nature of medication optimisation.

This research involved relatively little commitment from participants with intellectual disability and the intervention appeared acceptable in view of the recruitment metrics and response to the evaluation questionnaire. Two-thirds of psychiatrists thought the system should be used more extensively, indicating an overall favourable
attitude. In order to maintain proximity to usual practice, I gave psychiatrists flexibility and few instructions of how to use the online system in their appointments, other than on how to enter data. There was clearly variation in how different psychiatrists approached the HT-SMR; positive feedback showed that some appreciated the systematic and comprehensive nature of the medication review and believed that it could facilitate a discussion with the person with intellectual disability.

There was a degree of resistance to the HT-SMR that emerged in psychiatrist feedback. Negative comments referred to the perception that the structured review was inflexible and rigid. There is a recognised tension inherent in the increasingly structured nature of healthcare delivery and the desire of clinicians to preserve autonomy (Everson & Buntin, 2019). Some psychiatrists may have considered the method of medication review as a threat to their clinical autonomy, although this was not explicitly stated. This may be related to natural variation in clinicians’ consultation style and familiarity with incorporating standardised or structured elements to the consultation. The balance between a rigid, fully automated consultation and a loose, unstructured method is difficult to strike and any standard tool will need to be flexible enough to respond to patient and clinician preferences in this regard.

Some psychiatrists reported disruption to the relational aspects of the consultation arising from the need to interact simultaneously with the computer and the person with intellectual disability and others who may attend the appointment. Electronic
records are already used extensively in healthcare settings but use of technology as a more dynamic application may represent a more profound culture change and requires the development of new skills and ways of working (Castle-Clarke, 2018).

5.4.2 Strengths and limitations of this study

This study was completed in real-world settings, included psychiatrists of different grades from several different organisations and clinical services, and a diverse group of participants with intellectual disability, thereby increasing generalisability of the findings. It addresses a clear clinical and research need, that is, to develop and begin to formally test interventions that can promote medication optimisation in people with intellectual disability. I obtained estimates of important recruitment parameters and confirmed a recruitment strategy that could be replicated on a larger scale. Feedback has identified aspects of the HT-SMR which require development to improve the usability and utility of the intervention. The advantages of the HT-SMR are that it is relatively quick, self-explanatory, and can be completed in a single patient contact, potentially making it easier to integrate into current models of care than other published medication review methods that are multi-stage and multi-professional and hence likely to encounter implementation barriers (Scheifes et al., 2016; Zaal et al., 2016). Being conducted by the psychiatrist, who is also the prescriber, avoids the pitfalls of non-prescriber directed medication reviews in which as few as one-third of recommendations are actually instituted (Bach et al., 2017).

This study also had limitations. The HT-SMR was based on a pre-existing system which I had limited scope to alter. At the feasibility stage, however, this may be
acceptable, since the question was broadly whether this type of approach is worth pursuing. I could not collect the numbers or characteristics of those who declined to participate in the research, and therefore do not know the total eligible population or whether certain groups were under-represented in the sample. Similarly, I do not know the number of appointments in which the system could have been used in but was not, and without this denominator cannot report the rate of uptake. Attrition and clinician fatigue in using the online medication review may be an issue in a longitudinal study that was not addressed in this feasibility study, given the relatively short time-period of the research. A single participant feedback question was chosen to minimise demands placed on participants but was inevitably limited in scope and responses may have been subject to social desirability bias, especially since this question was asked by the person’s psychiatrist. Although logic suggests that the medication review would give patients and carers a greater opportunity for input in the process of medication decision-making, this was not formally tested and there was no method for gathering feedback from carers who may have been involved in the appointment and who play an important role in the medication process. The POTR scale (and the MEI thus derived) is not validated as a measure of medication effect in adults with intellectual disability, although it should also be noted that relatively few scales designed to assess medication effects have well-defined psychometric properties when applied to people with intellectual disability (de Kuijper & Hoekstra, 2016). As there was no control group, I do not know if there was greater propensity for clinicians to change medication as a result of the review (although clinicians in the feedback sensed that changes were more likely having undertaken the HT-SMR).
It cannot be assumed that the HT-SMR would function in the same way in other healthcare settings or patient groups. I included a limited number of psychiatrists, and within this group some were more enthusiastic users of the HT-SMR than others; this introduces a further source of bias, as the results are largely driven by only a small number of psychiatrists who used the system most often.

5.4.3 Future work

The HT-SMR concept could be expanded in two major directions. The first is to include an element of clinician decision support that may improve the evidence-base on which decisions are made. The second is to incorporate a patient-facing element to the tool with the aim of further embedding patient (and carer) views.

5.4.3.1 Clinician decision support

Clinician (or clinical) decision support (CDS) is a computerised intervention that occurs at the time and location of prescribing and supports prescribers with decision-making (National Institute for Health and Care Excellence, 2015b). CDS typically relies on electronic health systems and are designed to be incorporated into routine clinical care. Examples include alerts (e.g. to highlight high medication doses or duplicate therapy), reminders of clinical guidelines (e.g. the monitoring requirements of certain medications), or specific recommendations. Crude CDS systems for psychotropic medication review formed part of the ‘two stage’ medication review interventions described in the systematic review; prescribing that was outside certain parameters...
was electronically flagged and directed the person for more detailed clinician medication review.

The use of electronic health records provides an opportunity to develop more sophisticated CDS systems (Lavan et al., 2016; Rose et al., 2017). Electronic health records now contain a vast, and continually growing, repository of clinical data. The HT-SMR acts, in essence, as an electronic health record system. With sufficient users and medication reviews, a large and powerful naturalistic dataset would be created that includes clinical and demographic information, medication prescribed, and medication outcomes. This could be used to benchmark prescribing at individual, clinic, or regional level. Secondary research and machine learning algorithms could be applied to the datasets to show associations between given variables (e.g. between age or gender and medication outcomes) and to generate predictive models of medication effects (Peterson, 2019). This could be used to inform personalised medication plans for patients presenting with specific target symptoms, or who wished to avoid particular adverse side-effects.

To demonstrate how this might work in principle, I have included a table of selected data from individual medication reviews conducted as part of the feasibility study (table 5.3). I have chosen the three antipsychotic medications that were reviewed most frequently in the feasibility study.
Table 5.4 Consolidated Framework for Intervention Research as applied to a future iteration of the HealthTracker™-structured medication review

<table>
<thead>
<tr>
<th></th>
<th>Aripiprazole (n=16 reviews)</th>
<th>Risperidone (n=12 reviews)</th>
<th>Olanzapine (n=8 reviews)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target symptoms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyperactivity, impulsivity</td>
<td>n=5 Mean CGI-I 3.8</td>
<td>n=6 Mean CGI-I 3.0</td>
<td>n=1 Mean CGI-I 2.0</td>
</tr>
<tr>
<td>Anxiety</td>
<td>n=13 Mean CGI-I 3.1</td>
<td>n=8 Mean CGI-I 3.3</td>
<td>n=4 Mean CGI-I 2.8</td>
</tr>
<tr>
<td>Depressive mood</td>
<td>n=8 Mean CGI-I 2.8</td>
<td>n=2 Mean CGI-I 3.0</td>
<td>n=1 Mean CGI-I 2.0</td>
</tr>
<tr>
<td>Psychotic symptoms</td>
<td>n=8 Mean CGI-I 2.3</td>
<td>n=4 Mean CGI-I 3.3</td>
<td>n=5 Mean CGI-I 2.0</td>
</tr>
<tr>
<td><strong>Adverse side-effects</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GI symptoms</td>
<td>n=2/16 (13%) Mean severity = 1</td>
<td>n=1/12 (8%) Mean severity = 1</td>
<td>n=0/8 (0%) Mean severity = N/A</td>
</tr>
<tr>
<td>Sleep problems</td>
<td>n=3/16 (19%) Mean severity = 1.7</td>
<td>n=2/12 (17%) Mean severity = 1.5</td>
<td>n=3/8 (38%) Mean severity = 1</td>
</tr>
<tr>
<td>Over-eating / weight gain</td>
<td>n=3/16 (19%) Mean severity = 1</td>
<td>n=5/12 (42%) Mean severity = 1.4</td>
<td>n=4/8 (50%) Mean severity = 1.3</td>
</tr>
</tbody>
</table>

**Heatmap key**

Unfavourable response | Favourable response

Abbreviations: CGI-I, Clinical Global Impression-Improvement; GI, gastrointestinal

Note – CGI-I is scored on scale of 1 (very much improved) to 7 (very much worse)

Adverse side-effect severity is scored on scale of 1 (mild) to 3 (severe)

From table 5.3 it can be seen that, compared with the other antipsychotics in the table, aripiprazole is associated with least improvement (highest CGI) in treating hyperactivity/impulsivity. Olanzapine is associated with greatest improvement (lowest CGI) in management of psychotic symptoms. Similarly, over-eating/weight gain is most common with olanzapine, although gastro-intestinal side-effects occurred least often with the medication. Of course, to draw any reliable conclusions about medication effects would require far more data, and the results in this table
might be confounded by differences in dose or patient characteristics, but it is possible to envision, in principle, how this idea could be developed to provide suggestions for medication based on real-world data. This is especially important in intellectual disability psychiatry where, as I have described earlier in this thesis, there is a lack of experimental data from drug trials (and little prospect of future large, randomised controlled trials) and clinicians often rely on “best guess” and “trial and error” to make medication recommendations. As an addition, the GCI-I could be ‘weighted’ based on the relative importance that patients (and/or carers) place on specific medication effects, so that the ‘heatmap’ displayed in figure 5.3 is individualised to patient preference.

5.4.3.2 Patient-facing component

The HT-SMR could be developed to include a patient or carer portal. This might include a space where patients or carers can record illness variables and medication effects. If this is done regularly it will enable a more detailed picture of a person’s psychopathology and treatment response to be gathered. It has been suggested that giving patients the opportunity to track their health can contribute to a greater sense of ownership over their care (Mackert et al., 2016). Self-monitoring would also enable the clinician to review patient progress remotely and potentially release time in appointments for discussion and deliberation, as basic information gathering would already have occurred.

Patient decision aids (PDAs) provide information about treatment options and help to clarify personal values. A recent Cochrane review found good evidence that use of
PDAs enhances patient knowledge, increases participation in decision-making, and improves values-congruent choices (Stacey et al., 2017). It is possible that the HT-SMR could be designed to provide information and lead a person with intellectual disability through their options.

Various tools have been developed to act as PDAs and also to increase opportunities for SDM. Several interventions aim to rebalance power in the consultation by orientating the discussion towards the patient’s concerns, including wider aspects of a person’s life that can impact on their mental health, such as friendships and housing (Deegan et al., 2008; Moncrieff et al., 2016; Priebe et al., 2007). This may involve patients defining their concerns in a supported exercise (e.g. with a carer or family member) in advance of an appointment, committing these to paper, and the clinician then using this to direct the discussion. Some of these also include elements of CDS as integrated interventions (Henshall et al., 2017; Tasma et al., 2018). However, none of these interventions has been definitively tested those that have been used in clinical practice have suffered implementation barriers (Bonfils et al., 2018; Moncrieff et al., 2016; Priebe et al., 2017). Nevertheless, it is possible that similar approaches could be used with adults with intellectual disability and their carers.

The examples given above all include some degree of information technology. Digital interventions, if properly designed, can enhance understanding of people with intellectual disabilities, for example, by incorporating augmentative and alternative communication methods, such as visual aids and spoken as well as written information (Gibson et al., 2019; Huxley et al., 2015). Any patient-facing extension to
the HealthTracker™ system would need to incorporate features of universal design to optimise accessibility, such as incorporating a simple and logical user interface and screen magnifier options (Sheehan & Hassiotis, 2017a). It would also be necessary to co-designed the intervention closely with people with intellectual disability to ensure relevance and usability (Vereenooghe & Westermann, 2019).

5.4.3.3 Testing and implementing a future intervention

Any future system of structured medication review would need to be thoroughly tested before it was implemented as part of routine care. A cluster randomised controlled trial (RCT) with the unit of randomisation as a clinical team would be most appropriate (Lorenz et al., 2018). This would avoid contamination between health professionals delivering the intervention which could lead to a biased estimate of effect size. However, the cluster RCT design requires a greater number of participants which would necessarily impact the duration of the research and overall costs.

Several outcome measures would need to be used to reflect the different dimensions of medication optimisation. Measures of medication prescribing and adherence, treatment response, patient satisfaction and involvement in decision-making, as well as service utilisation and an economic evaluation, would all be relevant. Evaluating patient involvement in decisions and quantifying SDM is complex. A recent systematic review identified forty SDM measurement instruments but found none to be clearly superior and a general lack of evidence and validation (Gärtner et al., 2018). None had been developed or used in people with intellectual disability. Furthermore, most current instruments conceive SDM as a dyadic process, calling
into question the appropriateness of their use in situations where decision-making is distributed between a number of stakeholders.

The follow-up time of a trial would need to be sufficient for the medication review system to be used, medication changes instituted, and for the effects of any medication changes to be observed and recorded. Further work could include direct observation or recordings of consultations in which the HT-SMR was used to gain insight into how the HT-SMR is used in vivo and the ways in which it may influence the dynamics of the appointment. Due to the complexity of the work, an internal pilot study may be built in to the main trial.

The NHS is recognised to be a challenging environment in which to implement new ways of working (Collins, 2018), due in part to organisational and system-wide barriers including culture, lack of stability, lack of leadership, and lack of funding (de Silva, 2015). The NHS Innovation Accelerator has been established to improve uptake of healthcare innovations for patient and staff benefit (https://nhsaccelerator.com/) and Chief Clinical Information Officer roles have been created in most NHS Trusts to manage the implementation of technology-based interventions.

Designing and evaluating an intervention with reference to a formal implementation model can improve its likelihood of being adopted and contributing to better ways of working. A number of implementation theories exist; Damschroder et al (2009) reviewed nineteen of these and established an over-arching model, the Consolidated Framework for Implementation Research (CFIR), which is applicable across multiple
contexts and identifies five different levels at which determinants of implementation may operate (Damschroder et al., 2009). These are; the intervention characteristics, the outer setting, inner setting, individuals involved, and the implementation process. Within each domain are several constructs. Optimising conditions at each level is likely to pay dividends, although some may be out of the control of the researcher. The CFIR can be applied in any phase of implementation (i.e. pre-, during, or post-implementation). In table 5.4 I sketch out how insights from the CFIR may be used to identify potential barriers and facilitators to implementation of a future version of the HT-SMR.
Table 5.4 Consolidated Framework for Intervention Research as applied to a future iteration of the HealthTracker™-structured medication review

<table>
<thead>
<tr>
<th>CFIR domain</th>
<th>Constructs</th>
<th>Relevance to future versions of HT-SMR</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The background and nature of the intervention</td>
<td>Intervention complexity – composed of core and</td>
<td>• Balance complexity of HT-SMR with ease of use</td>
</tr>
<tr>
<td></td>
<td>peripheral components</td>
<td>• Build-in flexibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Adapt to local settings e.g. integrate HT-SMR with electronic health record</td>
</tr>
<tr>
<td></td>
<td>Evidence and relative advantage</td>
<td>• Use evidence to ‘sell’ the project – incl. anecdotal evidence, patient</td>
</tr>
<tr>
<td></td>
<td></td>
<td>experiences and results from the feasibility study</td>
</tr>
<tr>
<td></td>
<td>Intervention source</td>
<td>• Origin of system in response to a demonstrated clinical need</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Co-production with stakeholders to improve legitimacy</td>
</tr>
<tr>
<td>Inner setting</td>
<td>Structural characteristics</td>
<td>• Stable clinical teams will promote uptake</td>
</tr>
<tr>
<td></td>
<td>Implementation climate</td>
<td>• Engage organisational leaders e.g. senior managers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Commitment of local Chief Clinical Informatics Officers at research sites</td>
</tr>
<tr>
<td>Outer setting</td>
<td>External policies and incentives</td>
<td>• Invoke national policy e.g. STOMP</td>
</tr>
<tr>
<td>The economic, social, and political context within the organisation</td>
<td></td>
<td>• Refer to good practice guidelines and RCPsych and GMC professional standards</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Consider pay-for-performance incentives</td>
</tr>
<tr>
<td></td>
<td>Patient need</td>
<td>• Include views of experts by experience</td>
</tr>
<tr>
<td></td>
<td>Peer pressure</td>
<td>• Audit or benchmark reporting of medication use and review</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Scrutiny of prescribing from other stakeholders</td>
</tr>
<tr>
<td>Individuals involved in implementation</td>
<td>Attitudes towards the intervention</td>
<td>• Invest in building relationships with clinician users of HT-SMR</td>
</tr>
<tr>
<td>Characteristics of individuals who use or are affected by the intervention</td>
<td></td>
<td>• Utilise peer networks and assign ‘champions’ to promote the intervention</td>
</tr>
<tr>
<td></td>
<td>Knowledge and skill with the intervention</td>
<td>• Ensure adequate explanation of rationale</td>
</tr>
<tr>
<td></td>
<td>Self-efficacy</td>
<td>• Training on HT-SMR and availability of technical support</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Motivate stakeholders e.g. involve clinicians as co-researchers</td>
</tr>
<tr>
<td><strong>Implementation process</strong></td>
<td><strong>Planning</strong></td>
<td><strong>Executing</strong></td>
</tr>
<tr>
<td>---------------------------</td>
<td>--------------</td>
<td>---------------</td>
</tr>
</tbody>
</table>
| *Continuous review of implementation and rapid ‘work around’ of emerging barriers* | - Simulation or practice sessions  
- Introduce the intervention incrementally | - Provide targets and timelines for expected use  
- Regular researcher input and follow-up e.g. tracking HT-SMR use in real-time and providing targeted intervention where necessary | - Qualitative and quantitative feedback with reference to aims of project  
- An ongoing improvement process rather than at end of project only |

*Abbreviations: CFIR, consolidated framework for implementation research; HT-SMR, HealthTracker™-structured medication review; STOMP, Stopping The Over-Medication of People with learning disabilities, RCPsych, Royal College of Psychiatrists; GMC, General Medical Council*
5.5 Conclusion

Medication review has potential to improve individual and aggregate medication outcomes as part of a wider programme of medication optimisation. The HT-SMR is a feasible intervention that could be tested in a definitive trial in community psychiatry of intellectual disability teams. However, some refinement is necessary to improve integration with existing software and to fully embed patient and carer voice in the review process. Co-production techniques and focusing on implementation are important aspects of future work.
Chapter 6: Summary and overall conclusions

6.1 Summary of work

6.1.1 Context

Concerns about both the quality and quantity of psychotropic medication use for adults with intellectual disability have existed for several decades (Manchester, 1993; Singh et al., 1997). Anticipated reductions in psychotropic prescribing with deinstitutionalisation have not occurred (Agran & Martin, 1985; Kelly & Su, 2015; Nøttestad & Linaker, 2003) and the topic has become a defining feature of the care of individuals with intellectual disability. The quality of psychotropic medication use is now often used as a proxy indicator for the overall quality of care that people receive (Koch et al., 2018).

Judicious use of psychotropic medication is a priority for people with intellectual disability (Shaw, 2017), their supporters (Challenging Behaviour Foundation, 2016), and health and social care services (NHS, 2019; Voluntary Organisations Disability Group, n.d.). An array of professional bodies have publically committed to improving psychotropic use as part of the UK Stopping the Over-Medication of People with learning disabilities (STOMP) campaign.

STOMP may have helped to raise awareness of the issue of psychotropic over-prescribing to adults with intellectual disability but, notwithstanding anecdotal success stories, there remains little evidence that the initiative has influenced prescribing or materially affected patient outcomes on a national scale. Too narrow
a focus on quantitative measures of psychotropic medication use that do not account for complex individual circumstances, patient and carer preference, or the processes and experiences of medication use, can only ever have limited success.

Parallels can be drawn between STOMP and the UK Government strategy to reduce antipsychotic prescribing to people with dementia following evidence that use of these medications was associated with cardiovascular adverse events and increased mortality (Banerjee, 2009; Corbett et al., 2014). The ‘Call to Action’ in this case involved mandatory national audit and benchmarking of practice. Headline reductions in prescribing hailed the project a success (Health and Social Care Information Centre, 2012) although the long-term effects of the programme have been debated (Stocks et al., 2017; Szczepura et al., 2016); reductions in antipsychotic prescribing were not as great as anticipated and may have been short-term only (Stocks et al., 2017); might reflect a switch in medication from antipsychotic to other psychotropic compounds (Donegan et al., 2017; Maust et al., 2018); and could have had unintended consequences, for example, by denying people who might benefit access to medication (Ballard et al., 2015). Improving psychotropic medication use is a long-term commitment that needs to be founded on a solid evidence base and is probably less suited to time-limited or highly-centralised top-down interventions. Medication optimisation framework provides a potential framework for more sustainable improvements in medication use.

The aim of the work presented in this thesis was to investigate how the broad framework of medication optimisation could be applied to improve psychotropic
medication prescribing to adults with intellectual disability. I focused on two major
elements of medication optimisation; the first was patient involvement in medication
discussions and decisions; and the second was psychotropic medication review.
Neither of these aspects of medication optimisation had previously been well-
researched in adults with intellectual disability; my work adds to the literature and
suggests new avenues for exploration.

6.1.2 Qualitative work
There is a relative lack of qualitative work that addresses the views and experiences
of people with intellectual disability and carers related to psychotropic medication. I
have addressed this in the thesis with in-depth qualitative work drawing on the
experiences and views of multiple stakeholders. In particular, I considered the
involvement of adults with intellectual disability and carers in psychotropic
medication decision-making through the lens of SDM.

SDM, where patients and clinicians are recognised to possess equally valid forms of
knowledge, and decisions are based on patient preference and values as well as the
best available medical evidence, has become the pre-eminent and aspirational model
of healthcare decision-making in contemporary settings. Following a SDM approach
might fulfil the central role for patients (and, by extension, carers) in medication
discussions and decisions that medication optimisation demands.

A SDM approach to psychotropic medication decisions in adults with intellectual
disability is relevant and, although desired by many, is often not experienced by
people with intellectual disability and their carers. My findings suggest that the traditional model of SDM requires a degree of flexibility and adaptation in this context.

First, cognitive and communication limitations amongst people with intellectual disability call for extra attention to be paid to communication and information sharing in order to maximise the potential of people to understand and contribute to decisions. Whilst clinicians must be mindful of how information is presented during appointments, carers also have a role and can also use opportunities outside the consultation to repeat and reinforce knowledge. Even where information is provided optimally, there will remain a cohort of people with intellectual disability who lack capacity to make medication decisions. In these cases, SDM is not redundant but focus may shift to including family members or carers as active participants who can advocate for the person with intellectual disability based on intimate knowledge of their lives an appreciation of their likely wishes.

Second, shared decision-making is a two-way interaction (at least) and people with intellectual disability must be appropriately supported in discussions and deliberations with the psychiatrist. The uneven and deeply embedded power differentials that are experienced by people with intellectual disability (and also by people with mental illness) must be appreciated, and attempts made to dismantle these in order to allow people with intellectual disability to feel confident to contribute. This may involve informing people of their rights or the provision of structured tools that aim to re-orientate the content of the discussion from the
doctor’s agenda to the patient’s concerns. Even so, people with intellectual disability may choose not to avail themselves of greater involvement in medication decisions at certain points, and more directive approaches are needed at these times. A challenge seems to be distinguishing a genuine wish to delegate responsibility for decisions to others from a lack of engagement due to other factors, such as low self-efficacy or a history of lack of choice and oppression.

Third, the traditional SDM model has largely been developed with respect to a dyadic doctor-patient relationship and must therefore be adapted in the presence of multiple stakeholders. Sharing decisions between several individuals, each of whom may hold differing views and have differing preferences for the degree of involvement they wish to take, can make for complicated relational dynamics. Psychotropic medication decisions, which can be highly emotionally charged and imbued with meaning beyond that which would typically accompany medication for physical ailments, can be difficult for stakeholders to navigate, especially where there is insufficient research evidence on which to base opinions and the very nature of the condition being treated is debated. More formal training interventions that support different stakeholders, including psychiatrists, in their role within SDM could be one way of improving joint approaches to decision-making.

Finally, the wider environment needs to be conducive to SDM for psychotropic medication as systems factors impinge on both patient and clinician decisions to start, or their willingness to stop, prescribed medication (Anderson et al., 2014; Reeve et al., 2013). In addition, wider, systems changes, which are beyond the scope
of this discussion but are likely to include some re-organisation of health and social care services and additional financial investment, are necessary to achieve the goals of medication optimisation (Sheehan et al., 2017b) and a cultural shift such that medication is no longer viewed as the default for those with mental health problems and/or challenging behaviour is necessary.

6.1.3 Medication review systematic review

Medication review is purported to have a place in medication optimisation and is now included in several best-practice guidelines. Medication review focused on psychotropic medication had not previously been systematically studied. My review of focused psychotropic medication review interventions revealed a great deal of variety in how the intervention has been operationalised but little to indicate the necessary core elements or to guide the most effective methods of delivering the review.

Research exploring the role of focused psychotropic medication review in medication optimisation is of variable quality overall and there is little evidence at present to support its routine implementation; benefits in patient and clinical outcomes have not been consistently demonstrated. Face-to-face clinician medication review offers an obvious opportunity for patient (and carer) involvement, which has not been exploited in existing methods of medication review.
6.1.4 Structured medication review feasibility study

In the third study completed as part of this thesis, I tested the feasibility of instituting a novel, web-based tool to support medication review in community psychiatry of intellectual disability teams in the UK. This pragmatic method, underpinned by a logic model, offers several benefits that might result in improved psychotropic prescribing. Results of the feasibility study indicated that it would be possible to test the clinical and patient-reported outcomes of the medication review tool in a full-scale efficacy trial. There is, however, a need for further development to ensure the medication review tool reaches its potential as a means of promoting medication optimisation and strengthens the patient and carer voice in discussions.

6.2 Future directions

There is much scope for future theoretical and applied clinical research on medication optimisation and clear potential benefits for patient care. I have discussed specific aspects of future work in the relevant chapters, and provide an overview below.

It would be interesting to compare and contrast additional qualitative work on patient and carer experience of psychotropic medication from other regions or healthcare settings with my findings in order to build a more complete understanding of the issues. It would be of benefit if this work was undertaken by other researchers or research groups to avoid a particular narrative prevailing in the literature. Including people with intellectual disability or their carers more directly in the
process of data collection, analysis, and report-writing may also be of benefit in this regard.

Moving towards shared forms of decision-making is critically dependent on the attitudes and behaviours of psychiatrists. My study of psychiatrists was limited by the small number of focus groups that I was able to conduct and hence further work exploring their views is needed, particularly in order to address any underlying reservations they may have that could hinder practice change.

The SDM paradigm has not previously been applied to psychotropic medication decisions in adults with intellectual disability. I have suggested how the basics of the model may need to be adapted or emphasis changed in this context. Further work could explore this in more depth, possibly using direct observation and ethnographic techniques. This would help to refine models of shared decision-making, and could be extended to include any medical decisions (e.g. decisions about elective surgery) with adults with intellectual disability. Achieving a better understanding and an agreed working definition of SDM in this group could inform the development of measures of SDM that can be used as outcomes in future research that investigates interventions to strengthen the patient voice.

The strength of my systematic review findings are limited by the overall low quality of the existing literature; I have discussed specific deficits how these may be overcome in the relevant chapter, including agreeing clear definitions, strengthening reporting, and aligning outcome measures. This might be achieved with the creation
of a trans-national medication review research network to stimulate activity and encourage collaboration across centres.

Determining the optimum treatment of adults with intellectual disability and mental health problems and/or challenging behaviour will ultimately require more high-quality evidence of medication effects, and of the effects of other, psycho-social interventions that may be used as an alternative. However, this is a long-term endeavour and in the interim, pragmatic and feasible strategies are needed. Structured medication review is a direct clinical intervention that it is hoped could play a role in medication optimisation, and is available to impact patient care in the near future.

Using a tool, such as the HT-SMR, to guide information-gathering and to present data related to medication therapeutic effects and adverse side-effects systematically during the clinical encounter could lead to better and more rational decision-making. An explicit approach to medication review may be increasingly favoured as additional scrutiny is applied to prescribers, for example, through the Learning Disability Improvement Standards (NHS Improvement, 2018). I have discussed the possibilities for extending the tool to further improve decision-making and stakeholder involvement by incorporating artificial intelligence algorithms making use of the routine clinical data collected, and by re-structuring the consultation in a way that centres and amplifies the patient and carer voice.
Other aspects of medication optimisation that have not been addressed in this work could also form the basis of future study. These include developing systems for learning from medication incidents, such central reporting of adverse events and dissemination of learning, and ensuring that information related to medication (and medication changes) is accurately conveyed between services and providers in a timely manner (National Institute for Health and Care Excellence, 2015b).

6.3 Overall conclusions

A medication optimisation framework can be applied to improving psychotropic medication prescribing for adults with intellectual disability. My work demonstrates that collaborative medication decisions are achievable but not always experienced by adults with intellectual disability and their carers, and decision-making is subject to a number of influences that act at individual, relational, and at wider systems levels. There is a need to develop shared forms of decision-making that are responsive to the unique characteristics of this patient group; these should incorporate measures to maximise patient understanding and empowerment, include a clear place for other stakeholders, and adapt to varying preferences for involvement between individuals and over time.

Structured medication review is a pragmatic clinical intervention that has precedent in medication optimisation but which lacks definitive evidence of improved outcomes. The HealthTracker™ system of structured psychotropic medication review could be given additional functionality to support data-driven clinical recommendations and to promote patient and carer involvement in medication
discussions and decisions. It is feasible to test outcomes of such a system in a full-scale clinical trial in specialist mental health services for adults with intellectual disability.
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Appendices

Appendix 1 Qualitative study publication in BMJ Open
Appendix 2 Participant information sheet for qualitative study - participant with intellectual disability

Psychotropic medicines prescribing for people with intellectual disability: qualitative study

Participant information sheet

<table>
<thead>
<tr>
<th></th>
<th>My name is Rory Sheehan</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I work at University College London</td>
</tr>
</tbody>
</table>

I am a student doing some research

Research is when we ask people questions to find out things

What is our research about?

| | We are finding out about psychotropic medicines |

Psychotropic drug prescribing for people with intellectual disability - accessible participant information sheet, IRAS number 228696, version 3 (22/06/17)
<table>
<thead>
<tr>
<th>Psychotropic medicines are used to treat mental illness and sometimes other problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some people think we could use psychotropic medicines better with people with learning disabilities</td>
</tr>
<tr>
<td>We would like to talk to you if you take psychotropic medicines</td>
</tr>
<tr>
<td>We are interested in what you think about psychotropic medicine</td>
</tr>
<tr>
<td>We would like to know if you have been involved in decisions about your medicines and what is important to you</td>
</tr>
<tr>
<td>We want to think how we can make things better</td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>What will happen if I take part?</strong></td>
</tr>
<tr>
<td>If you agree to take part we will ask you to talk about psychotropic medicines with a researcher</td>
</tr>
<tr>
<td>We will talk to you alone or in a group of people</td>
</tr>
<tr>
<td>We will record the sound while people are talking</td>
</tr>
<tr>
<td><strong>Do I have to take part?</strong></td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td><img src="image" alt="Yes" /> <strong>You can tell us Yes</strong> if you want to take part</td>
</tr>
<tr>
<td><img src="image" alt="No" /> <strong>You can tell us No</strong> if you do not want to take part</td>
</tr>
<tr>
<td><img src="image" alt="Group" /> If you say <strong>no</strong> it will not change the care that you get</td>
</tr>
</tbody>
</table>
If you decide to take part we will ask you to sign a consent form

You can stop taking part at any time

What happens after you have seen me?

We will keep your information private on a computer that is secure

We will take out any personal information before anyone else can see it
We will give you a small gift to say thank you

We will send you a summary of what we found

What if I have more questions?

You can phone me. My phone number is [redacted]

You can email me. My email address is [redacted]
This research has been looked at by the Ethics Committee. They are there to make sure you are treated well.

University College London has also looked at this research. They are the sponsor.

If you are unhappy about something please tell us.

Thank you for looking at this leaflet.
Appendix 3 Participant information sheet for qualitative study – paid and family carer

Psychotropic medication prescribing for people with intellectual disability: qualitative study

Family carer participant information sheet

We would like to invite you to take part in our research study. Joining the study is entirely up to you but before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you to help you decide if you would like to take part. Please feel free to ask them questions about the study if you wish. Our contact details are at the end of this sheet. The study is being undertaken as part of a PhD degree.

Introduction

Many people with intellectual disability are prescribed psychotropic medication. Psychotropic medications are designed to treat mental illness. We know that some people with intellectual disability also receive these medications when they haven’t been diagnosed with a mental illness. In some cases they might be used for behaviour that challenges. There has been a lot of discussion about the best way to use psychotropic medications and many people believe that their use in people with intellectual disability can be improved.

Psychotropic medication – this is medication used for its effect on the way that people think, feel, and behave. It is often prescribed for people with a mental illness but it might also be given in other circumstances. Psychotropic medication includes antipsychotics, anti-depressants, mood stabilisers, sleeping tablets, sedatives, and stimulants.

Intellectual disability (also known as learning disability) – this term is used when a person has limitations in mental functioning and skills like communication, looking after themselves, and social skills. Some people with intellectual disability also have other conditions, like autism, mental illness, or physical health problems.

Purpose of this research

We want to help make sure that psychotropic medications are used in the best way possible for people with intellectual disability. We recognise that it is important to hear from those who support people with intellectual disability as they often play a vital role in many aspects of medication use, for example, helping to decide on when to start and stop medication, monitoring the effects of medication, and talking to the person with intellectual disability about their medication.

We want to hear the experiences of carers about when psychotropic medication has been prescribed and how it is reviewed. We also want to gather ideas about how prescribing these medications can be made better and involve people with intellectual disability and their carers more effectively. This work...
forms part of a student research project. The results will be published and widely disseminated and will hopefully go some way to improving practice.

Who can take part in the research?

You can take part if you support a family member or close friend who has an intellectual disability and has been prescribed psychotropic medication – these terms are explained in the box on the first page of this leaflet. You need to provide care for the person with intellectual disability and have attended health appointments with them but you do not need to be officially registered as their carer or to live with them.

What does the research involve?

If you are interested in taking part a member of our team will contact you to discuss the research. We will talk about the study in more detail and answer any questions you might have. If you agree to be involved you will be invited to an interview. This might be a group interview or an individual interview with a researcher. Before the interview we will explain the research again and will ask you to sign a consent form. The interview will last up to 90 minutes and we will record this with a voice recorder. We will arrange the interview at a time and place to suit you and will provide a £20 high-street voucher in recognition of your contribution to the research. We will provide drinks and refreshments at the group interviews.

We will discuss various things at the interview including your experiences of supporting your relative or friend to doctor’s appointments, how medication is discussed, and how decisions to start, continue, or stop psychotropic medications are made. You will be asked what you think should be taken into account when decisions about medication are made and how you and your relative or friend with an intellectual disability might be more involved in the process. We will ask you to comment on some materials that have been developed to help people thinking about the pros and cons of medication. There will be a chance for you to give your own ideas. You will not be asked to speak about anything that you are not comfortable with.

We are also speaking to people with intellectual disability. Your relative or friend may also wish to be involved in this study but there is no expectation that this will be the case.

Where will the research take place?

We will aim to arrange interviews to be most convenient for participants. Group interviews will take place at a local community centre or at University College London in central London. Individual interviews can take place at University College London or closer to your home or work.

What happens after the interviews?

After the interview your participation in the study will end. We will collect together all of the information and analyse it. When the research is complete we will write to you with a summary of what we found and what we plan to do next.

The study will give us important information that will be used to improve psychotropic medication prescribing for people with intellectual disability. We will present our results to doctors and other healthcare staff. The aim of this work is to enable people with intellectual disability and their carers to become more involved in medication decisions and to ensure that psychotropic medication is being used in the best way possible.
What will happen to the information collected during the study?

We will record the interviews with a voice recorder. The recordings will then be stored within UCL's 'data safe haven' which is a secure system that is accessible to the research team only. We will send the recordings to a company that converts the words into writing for us to analyse, but they will keep the information strictly confidential. Your personal details will not be shared with anyone else.

If we identify a serious risk of harm in the interview, we have a duty to share this information with the appropriate agencies. You will be told before we do this.

The overall findings from the study will be reported but you will not be identified. We might use parts of what you say in reports or scientific papers but these will be fully anonymised.

What are the risks and benefits of taking part?

There are few risks to participants. Participants in the group interviews might find it difficult to share their experiences and opinions, especially if this involves discussing difficult issues. We will deal with these issues sensitively. We will try to give everyone the chance to talk when they want to, but no-one will be forced to say anything if they would prefer not to. Before the group interviews we will remind everyone that the information discussed should be kept private but for the group interviews the researchers will not be able to guarantee full confidentiality of everything that is said.

We will keep all information secure and personal data will be handled in accordance with the Data Protection Act.

Participating in this research will give us more understanding of important issues and help us to develop ways of reviewing psychotropic medication that are most useful to people with intellectual disability and the people who support them. Participants might find that taking part in the research is interesting. Psychotropic medication use is a topic that many people care deeply about and participants might be keen to share their opinions and ideas about psychotropic medication prescribing for people with intellectual disability. Some people value hearing the thoughts of others and might learn new information from discussing the issues with a researcher or with the group.

Do I have to be involved?

No. It is up to you to decide if you wish to be involved in this study. Your decision will not affect the care that your relative receives.

Withdrawing from the study

You can decide at any time that you no longer want to be involved in the research. You do not have to give a reason. If you do decide to withdraw from the research we will not use any information that you might already have provided.

Who is organising and funding this study?

This study is organised by researchers at University College London (UCL). The study is funded by the National Institute for Health Research (NIHR) which is the research arm of the NHS.
Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Surrey Research Ethics Committee. University College London have also reviewed this study and are sponsoring the research.

What if there is a problem?

If you have any concerns about this research you can speak to Rory Sheehan (e-mail [redacted] or telephone [redacted]) who will do his best to help you.

In the unlikely event that a participant is harmed by taking part in this study and you suspect this is due to negligence then you may be able to claim compensation. Claims should be made in writing and sent to Professor Angela Hassiotis (e-mail [redacted] or telephone [redacted]) who is the Chief Investigator for the study.

Thank you for taking the time to read this leaflet.

Please contact us if you have any questions or would like to be involved. The Chief Investigator for this study is Professor Angela Hassiotis and the Principal Investigator is Dr Rory Sheehan.

Details of contact person

Name: Rory Sheehan
Address: [redacted]
E-mail address: [redacted]
Telephone: [redacted]

Details of Chief Investigator for this study

Name: Angela Hassiotis
Address: [redacted]
E-mail address: [redacted]
Telephone: [redacted]
Appendix 4 Participant consent form for qualitative study – participant with intellectual disability

Psychotropic drug prescribing for people with intellectual disability: qualitative study

Service user consent form

Participant Identification ...........

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<th>Yes</th>
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<tr>
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<td>I understand that it is my choice to take part</td>
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<tr>
<td>You can save information about what I say on a computer</td>
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<td></td>
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<tr>
<td>My name</td>
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<th>Researcher signature</th>
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*Page 4 of 4*

Psychotropic drug prescribing for people with intellectual disability – accessible participant consent form; IRAS number 225565, version 1 (29/04/17)
Appendix 5 Participant consent form for qualitative study – paid and family carer

Psychotropic drug prescribing for people with intellectual disability: qualitative study

Family or paid carer consent form

Participant Identification ............

| I have read and understood the information sheet about the study |
| I have had a chance to ask questions and talk about the study |
| I am happy with the answers to all of my questions |
| I understand that my participation is voluntary and I can stop being part of the study whenever I want to without giving a reason. It will not change the help that my relative or client receives |
| I agree to take part in an individual or group interview that will be audio recorded |
| I understand the information I provide will be kept confidential |
| I understand that the audio recording made will be used for analysis and anonymised extracts from my responses might be used in reports of the research |

Please initial each box
I agree to take part in this study

Name of participant: ...........................................................
Signature of participant: ..................................................
Date: .............................................................................

Name of researcher: .........................................................
Signature of researcher: ............................................... Date: .............................................................................
Appendix 6 Ethics approval for qualitative study

Health Research Authority
London - Surrey Research Ethics Committee
Whitkehams
Level 2, Block B
Lawrence Mead
Bristol
BS1 3NT

Telephone: 02071048035/35

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval.

19 September 2017
Professor Angela Hassiotis

Dear Professor Hassiotis,

Study title: Investigating decision making and choice in psychotropic drug prescribing for people with intellectual disability: qualitative study
REC reference: 17/LO/1385
IRAS project ID: 225595

The Research Ethics Committee reviewed the above application at the meeting held on 05 September 2017. The Committee found it helpful that Dr Rory Sheehan could attend to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

281
Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).


Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non-registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHSHSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).
Summary of discussion at the meeting

Social or scientific value, scientific design and conduct of the study

The Committee requested Dr Sheehan to explain if the carers or relatives could influence or change the treatment of the patients. Dr Sheehan explained that the input of the carers or family members may potentially influence or change the medication and this is what they will try to investigate. He explained that one of the aims of the study is to understand and hear and document the opinions of these carers and family members who may feel disempowered.

The Committee asked Dr Sheehan what will happen if they get a negative outcome. Dr Sheehan explained that they will note the comments and report them.

Favourable risk benefit ratio, anticipated benefit/risks for research participants (present and future)

The Committee requested Dr Sheehan to clarify how they will assess the mental capacity of the potential participants and how will they confirm cognitive competence. Dr Sheehan explained that they will recruit the participants through the clinical services and therefore the initial capacity check would have been done by the usual clinical care team. The clinicians will also be informed that the study will only recruit participants who have capacity to consent. There will be a further assessment based on the principles of mental Capacity Act at the time of taking consent. This assessment will be carried out by Dr Sheehan and he regularly assess patients for mental capacity. The Committee was satisfied with the explanation provided.

Care and protection of research participants, respect for potential and enrolled participants' welfare and dignity

The Committee expressed concerns that potential participants may be looking forward to take part in the study and they may be disappointed when they are turned them. Dr Sheehan acknowledged the concerns of the Committee and explained that he will approach them sensitively and thank them for their interest.

The Committee queried if there will be other people like carers of the patients with intellectual disabilities may also take part in the study and may be present during the focus groups. Dr Sheehan explained that there may be cases where carers may be in the study but they will not talk to the carers at the same time during the focus groups.

Informed consent process and the adequacy and completeness of participant information

The Committee commended Dr Sheehan for submitting very clear and well-presented Information Sheets. Professor Dr Sheehan thanked the Committee.

Please contact the REC Manager if you feel that the above summary is not an accurate reflection of the discussion at the meeting.

Approved documents

The documents reviewed and approved at the meeting were:
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Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

There were no declarations of interest
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website, http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

17/LO/1365 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project.

Yours sincerely

pp Mrs Chrissee Lawson Chair

E-mail: nrescommittee.secoast-surrey@nhs.net

Enclosures: List of names and professions of members who were present at the
Appendix 7 Topic guide for individual semi-structured interviews with adults with intellectual disability

*To be supplemented with visual information and prompts*

- What do you think about the medication you take for mental health?

- Do you talk about psychotropic medication with the psychiatrist?
  - What has this been like?
  - Do they ask what has been good about taking medication?
  - Do they ask what has been bad about medication?

- Who is involved in decisions about psychotropic medication?
  - Do you want to be involved?
  - Are you involved?
    - If not, why?
  - Is anyone else involved (e.g. carer, family member)?
    - How are they involved?
    - What do you think about them being involved?

- Do you feel that you have a choice about medication?
  - Does the psychiatrist ask you what you want to do with medication?
  - Have they listened to your views?

- What if you were worried about your medication?
  - What if you had a problem with your medication?

- What should the doctor think about when they are prescribing medication for you?
  - What is important to you?
  - What do you want to know about the medicine?

- What would make it easier to talk to the doctor about medication?
Appendix 8 Topic guide for individual semi-structured interviews with family carers of adults with intellectual disability

- What has been your experience when psychotropic medication has been prescribed for your relative?

- Who is involved in decisions about psychotropic medication?
  - How is your relative involved in the decision?
  - Are you involved?
  - Who else is involved?
  - Is/was your level of involvement what you would like?

- Is medication reviewed after it has been prescribed?
  - How?
  - What was the review like?
  - Are you involved in this?
  - Is the review effective?

- How were/are decisions to continue, stop, or change medication made?
  - Have you and your relative been given a choice about medication?

- Do you discuss medication with the psychiatrist at appointments?
  - Do you think that you know enough about the medications?
  - How would you know if medication is working or not working?
  - Do you have a method for recording the positive and negative effects of medication (e.g. rating scales)?
  - What if there is a problem with medication?

- What should be thought about when medication is reviewed?

- What might make it easier for you or your relative to give your views about medication?
Appendix 9 Topic guide for individual semi-structured interviews with paid carers of adults with intellectual disability

- What has been your experience when psychotropic medication has been prescribed for the people you support?

- Who is involved in decisions about psychotropic medication?
  - How is the person you support involved in the decision?
  - Are you involved?
  - Should you be involved?

- Is medication reviewed after it has been prescribed?
  - How?
  - What happens in the review?
  - Are you involved in this?
  - Is the review effective?

- Who makes decisions to continue, stop, or change medication?
  - How are these decisions made?
  - Have you and the person you support been given a choice about medication?

- Do you discuss medication with the psychiatrist at appointments?
  - How able do you feel to contribute to this discussion?
  - Do you think that you know enough about the medications?
  - How would you know if medication is working or not working?
  - Do you have a method for recording the positive and negative effects of medication (e.g. rating scales)?
  - What if there is a problem with medication?

- What should be thought about when medication is reviewed?

- What might make it easier for you or the person you support to give your views about medication?
Appendix 10 Participant information sheet for qualitative study – psychiatrist

Psychotropic medication prescribing for people with intellectual disability: qualitative study

Psychiatrist participant information sheet

We would like to invite you to take part in our research study. Joining the study is entirely up to you but before you decide we would like you to understand why the research is being done and what it would involve for you. Please read this sheet carefully and one of our research team will be available to answer any questions that you might have. Our contact details are at the end of this sheet. The study is being undertaken as part of a PhD degree.

Introduction

The use of psychotropic medication for people with intellectual disability (ID) continues to receive attention. Various political, professional, and patient organisations have called for improvements in the way that psychotropic medication is prescribed and monitored in people with ID.

Purpose of this research

We want to investigate experiences of psychotropic medication prescribing and medication review in people with ID. A key part of this is gathering the views of prescribers. We are particularly interested in the process of medication review and how this can be improved in order to optimise medication prescribing. We would like to hear ideas from front-line professionals about improving medication reviews in people with ID. Ultimately we aim to develop a tool that can support psychotropic medication review and we would like clinician’s views about prototype versions of this.

Who can take part in the research?

You are eligible to take part in this research if you are a psychiatrist (of any grade) who works in a community team for adults with intellectual disability.

What does the research involve?

If you are interested in taking part in this research a member of our research team will discuss this with you in more detail. We will then invite you to an interview. You will be asked to sign a consent form before taking part in the research.

The interview might be an individual interview or a focus group with up to 6 participants. We will discuss various topics related to psychotropic prescribing, medication review, and ask for your experience and ideas. The interview will be recorded with a voice recorder.

We will present materials that have been developed to support psychotropic medication review and decision making and ask your opinion of these and how they might be improved, if we wished to use them in routine clinical practice.
We will not ask you to speak about anything that you are not comfortable in doing so and we will not ask you to disclose any confidential patient information.

Where will the research take place?

We will arrange the interviews at a time and place that is most convenient for participants.

What happens after the interviews?

After the interview your participation in the study will end. We will collect together all of the information and analyse it using qualitative methodology. When the research is complete we will write to you with a summary of the results and how these will inform the next stages of our research.

What will happen to the information collected during the study?

We will record the interviews with an audio recorder. These will then be stored within UCL’s ‘data safe haven’ which is a secure system that is accessible to the research team only. We will send the recordings to an external transcription company but the data will be kept strictly confidential at all times. Your personal details will not be shared with anyone else.

In line with our professional duty, in the unlikely occurrence that we identify a serious risk of harm from what is said in the interview, we have a duty to share this information with the appropriate agencies. You will be told before we do this.

The overall findings from the study will be reported but you will not be identified. We might use parts of what you say in the reporting but any quotes will be fully anonymised.

What are the risks and benefits of taking part?

We anticipate very few risks for professionals taking part in this research. Before the focus group we will remind everyone that the information discussed should be kept private but the researchers will not be able to guarantee full confidentiality of everything that is said. We will keep all information secure and personal data will be handled in accordance with the Data Protection Act.

The use of psychotropic medication for people with ID has been a controversial topic. Taking part in this research will give participants a chance to share their thoughts in a forum that is intended to improve the knowledge base in this area and drive positive changes in policy and practice.

Do I have to be involved?

No. It is up to you to decide if you wish to be involved in this study.

Withdrawing from the study

You can decide at any time that you no longer want to be involved in this research. You do not have to give a reason. If you do decide to withdraw from the research we will not use any information that you might already have provided.

Who is organising and funding this study?

This study is organised by researchers at University College London (UCL). The study is funded by the National Institute for Health Research (NIHR).
Who has reviewed this study?

This study has been reviewed and given a favourable opinion by (TBC) NHS Research Ethics Committee. The sponsor of this study is University College London.

What if there is a problem?

If you have any concerns about this research you can speak to Rory Sheehan (e-mail [redacted] or telephone [redacted]) who will do his best to help you.

In the unlikely event that a participant is harmed by taking part in this study and you suspect this is due to negligence then you may be able to claim compensation. Claims should be made in writing and sent to Professor Angela Hassiotis (e-mail [redacted] or telephone [redacted]) who is the Chief Investigator for the study.

Thank you for taking the time to read this leaflet.

Please contact us if you have any questions or would like to be involved. The Chief Investigator for this study is Professor Angela Hassiotis and the Principal Investigator is Dr Rory Sheehan.

Details of contact person

Name: Rory Sheehan
Address: [redacted]
E-mail address: [redacted]
Telephone: [redacted]

Details of Chief Investigator for this study

Name: Angela Hassiotis
Address: [redacted]
E-mail address: [redacted]
Telephone: [redacted]
Psychotropic drug prescribing for people with intellectual disability: qualitative study

Psychiatrist consent form

Participant Identification ..............  

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</tr>
<tr>
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</tr>
<tr>
<td>I am happy with the answers to all of my questions</td>
<td></td>
</tr>
<tr>
<td>I understand that my participation is voluntary and I can stop being part of the study whenever I want to without giving a reason.</td>
<td></td>
</tr>
<tr>
<td>I agree to take part in an individual or group interview that will be audio recorded</td>
<td></td>
</tr>
<tr>
<td>I understand the information I provide will be kept confidential</td>
<td></td>
</tr>
<tr>
<td>I understand that the audio recording made will be used for analysis and anonymised extracts from my responses might be used in reports of the research</td>
<td></td>
</tr>
<tr>
<td>I agree to take part in this study</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 12 Topic guide for psychiatrist focus groups

- How are decisions about psychotropic medication made?

- What is your role as the psychiatrist?
  - What might make it easier or more difficult?
  - Do you always have the information you need?

- Who is involved and how do they contribute?
  - Person with ID – how much can they be involved? Do they want / expect to be involved? Do insight and cognitive limitations play a role?
  - Family
  - Carer
  - Other professionals

- Is involvement always a good thing? Does it help or hinder?

- What is the possibility for making shared (collaborative) decisions for psychotropic medications?
  - Is it appropriate in this context (ID and psychotropic medications)
  - Facilitators / barriers
  - Challenges and what works well in including others?

- Is there always a choice in treatments?

- Is there anything different in this group compared to others you’ve worked with?

- What happens if there is disagreement?
  - How might this be resolved?
  - Who has the final say?

- Are there other things you would like to say before we finish?
Appendix 13 Systematic review publication in JAMA Network Open
### Appendix 14  Systematic review example full search strategy (PsycINFO, American Psychological Association)

<table>
<thead>
<tr>
<th>Search term and limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (medication* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>2 (drug* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>3 (prescri* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>4 (medication* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>5 (drug* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>6 (prescri* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>7 (medication* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>8 (drug* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>9 (prescri* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>10 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9</td>
</tr>
<tr>
<td>11 psychotropic*.ti,ab</td>
</tr>
<tr>
<td>12 Anti?psychotic*.ti,ab</td>
</tr>
<tr>
<td>13 neuroleptic*.ti,ab</td>
</tr>
<tr>
<td>14 major tranquil?i#er*.ti,ab</td>
</tr>
<tr>
<td>15 mood stabilizer#.ti,ab</td>
</tr>
<tr>
<td>16 anti?depressant*.ti,ab</td>
</tr>
<tr>
<td>17 sedative*.ti,ab</td>
</tr>
<tr>
<td>18 hypnotic*.ti,ab</td>
</tr>
<tr>
<td>19 anxiolytic*.ti,ab</td>
</tr>
<tr>
<td>20 minor tranquil?i#er*.ti,ab</td>
</tr>
<tr>
<td>21 &quot;neuroleptic drugs&quot;/</td>
</tr>
<tr>
<td>22 &quot;mood stabilizers&quot;/</td>
</tr>
<tr>
<td>23 &quot;antidepressant drugs&quot;/</td>
</tr>
<tr>
<td>24 &quot;hypnotic drugs&quot;/</td>
</tr>
<tr>
<td>25 &quot;sedatives&quot;/</td>
</tr>
<tr>
<td>26 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25</td>
</tr>
<tr>
<td>27 (psychotropic* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>28 (anti?psychotic* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>29 (neuroleptic* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>30 (major tranquil?i#er* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>31 (mood stabilizer#.er adj2 review*).ti,ab</td>
</tr>
<tr>
<td>32 (anti?depressant* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>33 (sedative* adj2 review*).ti,ab</td>
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<tr>
<td>34 (hypnotic* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>35 (anxiolytic* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>36 (minor tranquil?i#er* adj2 review*).ti,ab</td>
</tr>
<tr>
<td>37 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36</td>
</tr>
<tr>
<td>38 (psychotropic* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>39 (anti?psychotic* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>40 (neuroleptic* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>41 (major tranquil?i#er* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>42 (mood stabilizer#.er adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>43 (anti?depressant* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>44 (sedative* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>Search term and limits</td>
</tr>
<tr>
<td>------------------------</td>
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<tr>
<td>45 (hypnotic* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>46 (anxiolytic* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>47 (minor tranquil?i#er* adj2 optimi#ation).ti,ab</td>
</tr>
<tr>
<td>48 38 OR 39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45 OR 46 OR 47</td>
</tr>
<tr>
<td>49 (psychotropic* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>50 (anti?psychotic* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>51 (neuroleptic* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>52 (major tranquil?i#er* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>53 (mood stabilili#er* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>54 (anti?depressant* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>55 (sedative* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>56 (hypnotic* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>57 (anxiolytic* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>58 (minor tranquil?i#er* adj2 monitoring).ti,ab</td>
</tr>
<tr>
<td>59 49 OR 50 OR 51 OR 52 OR 53 OR 54 OR 55 OR 56 OR 57 OR 58 OR 59</td>
</tr>
<tr>
<td>60 37 OR 48 OR 59</td>
</tr>
<tr>
<td>61 10 AND 26</td>
</tr>
<tr>
<td>62 60 OR 61</td>
</tr>
</tbody>
</table>
## Appendix 15 Quality assessment of controlled intervention studies

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes</th>
<th>No</th>
<th>Other (C, R, H, HA*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the study described as randomized, a randomized trial, an randomized clinical trial, or an RCT?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Was the method of randomization adequate (i.e., use of randomly generated assignment)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Was the treatment allocation concealed so that assignments could not be predicted?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Were study participants and providers blinded to treatment group assignment?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Were the people assessing the outcomes blinded to the participants’ group assignments?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?</td>
<td></td>
<td></td>
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<tr>
<td>8. Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?</td>
<td></td>
<td></td>
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<tr>
<td>9. Were there high adherence to the intervention protocols for each treatment group?</td>
<td></td>
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</tr>
<tr>
<td>10. Were other interventions avoided or similar in the groups (e.g., similar background treatments)?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>13. Were outcomes reported or subgroups analyzed post-hoc, i.e., identified before analyses were conducted?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 16 Quality assessment of before-after studies with no control group

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes</th>
<th>No</th>
<th>Other (CB, NR, NA)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Was the study question or objective clearly stated?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Were eligibility criteria for the study population specified and stated?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Were the participants in the study representative of those who would be eligible for the intervention in the general or clinical population of interest?</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>4. Were all eligible participants that met the specified eligibility criteria enrolled?</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>5. Was the sample size sufficiently large to provide confidence in the findings?</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6. Was the intervention clearly described and delivered consistently across the study populations?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Were the outcome measures specified, clearly defined, valid, reliable, and assessed consistently across all study participants?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Were the people assessing the outcomes blinded to the participants' exposure to interventions?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided p-values for the pre-to-post changes?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention? (i.e., did they use an interrupted time-series design?)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.), did the statistical analysis take into account the use of individual-level data to determine effects at the group level?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 17 PRISMA flow diagram – original search (conducted 14.02 2018)

Identification
- 21 additional articles identified through other sources
- 9,464 citations identified (Medline 3010; EMBASE 3871; PsycINFO 1461; CINAHL plus 1,622)
- 3,043 duplicates removed

Screening
- 6,442 titles screened
- 5,886 citations excluded on title
- 508 citations excluded on abstract

Eligibility
- 48 studies for full text review
- 21 citations excluded after full text review
  - No medication review intervention (n=3)
  - Not focused psychotropic review (n=8)
  - Multi-modal intervention (n=4)
  - No optimisation outcome (n=5)
  - Short report (n=1)

Review
- 27 studies included in review (8,556 participants)
- 3 studies included in meta-analysis (652 participants)
Appendix 18 PRISMA flow diagram – updated search (conducted 31.08.2019)

810 citations identified (Medline 247; EMBASE 415; PsycINFO 41; CINAHL Plus 107)

- 239 duplicates removed
- 571 titles screened
- 525 citations excluded on title
- 46 abstracts reviewed
- 37 citations excluded on abstract
- 9 studies for full text review
- 9 citations excluded after full text review
  - No medication review intervention (n=1)
  - Not focused psychotropic review (n=2)
  - Multi-modal intervention (n=1)
  - No optimisation outcome (n=2)
  - Conference abstracts (n=3)

0 studies included in review
### Appendix 19 Full data tables of data extracted from studies included in systematic review

#### Randomized controlled trials

<table>
<thead>
<tr>
<th>Ballard et al, 2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study title</strong></td>
</tr>
<tr>
<td><strong>Study design</strong></td>
</tr>
<tr>
<td><strong>Location</strong></td>
</tr>
<tr>
<td><strong>Setting</strong></td>
</tr>
<tr>
<td><strong>Number of participants</strong></td>
</tr>
<tr>
<td><strong>Participant characteristics</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td><strong>Duration of follow-up</strong></td>
</tr>
<tr>
<td><strong>Optimisation outcome measures and results</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Author’s conclusions</strong></td>
</tr>
<tr>
<td><strong>Source of funding</strong></td>
</tr>
<tr>
<td><strong>Quality assessment</strong></td>
</tr>
<tr>
<td><strong>Critical appraisal</strong></td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

\(^a\)NICE, National Institute for Health and Care Excellence; \(^b\)OR, odds ratio; \(^c\)NPI, neuro-psychiatric inventory
### Ballard et al, 2017

<table>
<thead>
<tr>
<th>Category</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study title</strong></td>
<td>Impact of antipsychotic review and non-pharmacological intervention on health-related quality of life in people with dementia living in care homes: WHELD – a factorial cluster randomised controlled trial</td>
</tr>
<tr>
<td><strong>Study design</strong></td>
<td>Factorial cluster-randomized controlled trial (reports secondary outcome of Ballard et al, 2016a)</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>UK</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Sixteen nursing homes</td>
</tr>
<tr>
<td><strong>Number of participants</strong></td>
<td>n=277</td>
</tr>
<tr>
<td><strong>Participant characteristics</strong></td>
<td>People with dementia (12% mild, 40% moderate, 47% severe) Mean (SD) age 85.3 (7.02) years 74% female 18% prescribed antipsychotic medications</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>Multi-modal (impact of medication review reported separately); all nursing homes received training in person-centered care and were then randomized to a combination of, antipsychotic medication review, social interaction intervention, and an exercise intervention. Antipsychotic review based on guidelines from NICE(^a), Alzheimer’s Society, and the UK Department of Health and delivered by participants’ usual physician (general practitioner or psychiatrist). Selected staff in each home were encouraged to prompt medication review in those suitable.</td>
</tr>
<tr>
<td><strong>Duration of follow-up</strong></td>
<td>9 months</td>
</tr>
</tbody>
</table>
| **Optimisation outcome measures and results** | Health-related quality of life (measured with DEMQOL-proxy)  
Those receiving medication review showed a 4.54 point (95% CI -9.26 to 0.19, p=0.06) worsening in their DEMQOL-proxy score at follow-up compared with those in control group |
| **Author’s conclusions**         | Medication review and subsequent antipsychotic discontinuation had a detrimental impact on health-related quality of life                                                                                     |
| **Source of funding**            | National Institute for Health Research                                                                                                                                                                       |
| **Quality assessment**           | Good                                                                                                                                                                                                         |
| **Critical appraisal**           | Lack of blinding  
Intervention varied or poorly described  
Control condition not well described  
High attrition  
Multiple testing                                                                                                                    |

\(^a\)NICE, National Institute for Health and Care Excellence

### Jordan et al, 2015

<table>
<thead>
<tr>
<th>Category</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study title</strong></td>
<td>Nurse-led medicines’ monitoring for patients with dementia in care homes</td>
</tr>
<tr>
<td><strong>Study design</strong></td>
<td>Pragmatic cohort stepped wedge cluster randomized trial</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>UK</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Five nursing homes</td>
</tr>
<tr>
<td><strong>Number of participants</strong></td>
<td>n=41</td>
</tr>
</tbody>
</table>
| **Participant characteristics**  | People with dementia prescribed a psychotropic, anti-depressant, or anti-epileptic medication  
Mean (SD) age 78.7 (11.0) years  
61% female                                                                                                                                 |
| **Intervention**                 | Monthly nurse-led medication review by application of West Wales Adverse Drug Reaction Profile for Mental Health Medicines                                                                                 |
| **Duration of follow-up**        | 5 months                                                                                                                                                                                                     |
Optimisation outcome measures and results

**Number of medication-related problems identified**
More problems were identified when the Profile was used compared with not used (adjusted mean difference 9.06, 95%CI 7.95 to 10.16)

**Actions to address medication-related problems identified**
Problems were actioned more frequently when the Profile was used compared with not used (adjusted mean difference 3.34, 95%CI 2.57 to 4.11)

**Changes in psychotropic medication**
Reductions in mental health medicines were more likely when the Profile was used compared with not used (adjusted OR\(^b\) 4.45, 95% CI 1.15 to 17.22)

**Functional status (measured with Bristol ADL\(^c\) scale)**
No significant difference between intervention and control (mean difference between groups 0.45, 95%CI -0.47 to 0.93, p=0.52)

**Dementia psychopathology (measured with MOUSEPAD\(^d\))**
No significant difference between intervention and control (mean difference between groups 4.67, 95%CI -0.04 to 2.78, p=0.06)

Author’s conclusions
Nurse-led medication review using the WWADR increased the numbers of medication-related problems identified and addressed and reduced prescriptions of psychotropic medications. The intervention is feasible, low cost, low risk, and convenient.

Source of funding
Wales School for Primary Care Research

Quality assessment
Fair

Critical appraisal
Selection bias
Lack of blinding
Use of unvalidated measures / non-standard assessment tools
Small sample
Intervention varied or poorly described
Multiple testing

\(^{a}\) CI, confidence interval; \(^{b}\) OR, odds ratio; \(^{c}\) ADL, activities of daily living; \(^{d}\) MOUSEPAD, Manchester and Oxford Universities Scale for the Psychopathological Assessment of Dementia

---

**Moncrieff et al, 2016**

<table>
<thead>
<tr>
<th>Study title</th>
<th>Results of a pilot cluster randomised trial of the use of a medication review tool for people taking antipsychotic medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Cluster randomized controlled trial (pilot study)</td>
</tr>
<tr>
<td>Location</td>
<td>UK</td>
</tr>
<tr>
<td>Setting</td>
<td>Community psychiatric teams</td>
</tr>
<tr>
<td>Number of participants</td>
<td>(n=60)</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Adults with a psychotic disorder taking antipsychotic medication Mean age 42.1 years 72% male</td>
</tr>
<tr>
<td>Intervention</td>
<td>A Medication Review Tool to be completed by participants (with support, if needed) prior to a psychiatrist appointment to guide discussion about antipsychotic medication</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>3 months</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td>Decision Self-Efficacy Scale No significant difference between intervention and control group (adjusted difference -4.16, 95%CI -9.81 to 1.49) Client Satisfaction Questionnaire No significant difference between intervention and control group (mean score 27 in intervention group, 28 in control group, p&gt;0.05) Drug Attitude Inventory</td>
</tr>
</tbody>
</table>

---

304
No significant difference between intervention and control groups (adjusted difference 1.65, 95%CI -0.09 to 3.40)

**Liverpool University Neuroleptic Side-Effect Rating Scale**
No significant difference between intervention and control groups (adjusted difference -0.42, 95%CI -8.12 to 7.29)

**Brief Positive and Negative Syndrome Scale**
No significant difference between intervention and control groups (adjusted difference 0.13, 95%CI -2.21 to 2.48)

**Medication Adherence Questionnaire**
Participants in the intervention group had a lower score indicating greater propensity to be adherent with medication (adjusted difference -0.44, 95%CI -0.76 to -0.11)

**Change in antipsychotic medication**
No significant difference between intervention and control groups (OR\(^b\) 2.64, 95% CI 0.84, 8.31)

**Antipsychotic polypharmacy (≥2 antipsychotics prescribed)**
No difference between intervention and control groups

<table>
<thead>
<tr>
<th>Author's conclusions</th>
<th>The Medication Review Tool did not improve participants' confidence in decisions about their antipsychotic medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source of funding</td>
<td>National Institute for Health Research</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Good</td>
</tr>
</tbody>
</table>

| Critical appraisal     | Selection bias  
|                        | Baseline differences between intervention and control group  
|                        | Lack of blinding  
|                        | Intervention varied or poorly described  
|                        | Multiple testing  
|                        | Possible contamination of control group  
|                        | Pilot study not powered to detect difference in outcome measures                                      |

\(^a\)Additional data provided by authors; \(^b\)OR, odds ratio

**Patterson et al, 2010**

<table>
<thead>
<tr>
<th>Study title</th>
<th>An evaluation of an adapted US model of pharmaceutical care to improve psychoactive prescribing for nursing home residents in Northern Ireland (Fleetwood Northern Ireland Study)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Cluster randomized controlled trial</td>
</tr>
<tr>
<td>Location</td>
<td>UK</td>
</tr>
<tr>
<td>Setting</td>
<td>Twenty two nursing homes</td>
</tr>
<tr>
<td>Number of participants</td>
<td>(n=334)</td>
</tr>
</tbody>
</table>
| Participant characteristics | Older adults  
|                        | Mean (SD) age 82 (8.4) years  
|                        | 73% female  
|                        | 68% moderately-severely cognitively impaired  
|                        | 71% prescribed psychotropic medication                                                                                                                                                     |
| Intervention | Face-to-face monthly medication review by study pharmacist. Algorithm was used to indicate inappropriate psychotropic medication. Pharmacist recommendations for medication changes discussed with General Practitioner. |
| Duration of follow-up | 12 months                                                                                                                                 |
| Optimisation outcome measures and results | Proportion of nursing home residents prescribed ≥1 inappropriate psychotropic medication at follow-up  
|                        | Significantly lower proportion prescribed inappropriate psychotropic medications in intervention group compared with the control group at follow-up (intervention group proportion: 20%, control group proportion: 50%, p<0.001; adjusted OR\(^a\) for receiving inappropriate psychotropic medication 0.26 (0.14 to 0.49))  
|                        | Rate of falls                                                                                                                                 |

305
No significant difference in rate of falls between intervention and control groups (intervention group rate: 16.3 falls per 100 person-months, control group rate: 11.4 falls per 100 person-months, \( p=0.09 \))

**Author’s conclusions**

A pharmacist-delivered program of medication review targeting specific medications can result in marked reduction in inappropriate psychotropic medication prescribing but had no effect on falls.

**Source of funding**

Health and Social Care Research and Development Office Health and Social Services Boards, Northern Ireland

**Quality assessment**

Fair

**Critical appraisal**

Baseline differences between intervention and control group
Lack of blinding
Use of unvalidated measures / non-standard assessment tools (secondary outcome)
High attrition

*OR, odds ratio

**Before-after studies**

<table>
<thead>
<tr>
<th>Study title</th>
<th>Improving nursing home compliance via revised antipsychotic use survey tool</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study design</strong></td>
<td>Before-after</td>
</tr>
<tr>
<td><strong>Location</strong></td>
<td>USA</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Two nursing homes</td>
</tr>
<tr>
<td><strong>Number of participants</strong></td>
<td>( n=20 )</td>
</tr>
<tr>
<td><strong>Participant characteristics</strong></td>
<td>People with dementia (and without a psychotic or mood disorder) prescribed antipsychotic medication for behavioral and psychological symptoms Mean (SD) age 87.1 (7.9) years 90% female</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>Monthly medication reviews by a pharmacist using a modified version of the CDPH antipsychotic use tool designed to improve compliance with prescribing guidelines. Pharmacist made recommendations to the prescribing physician who made treatment decisions</td>
</tr>
<tr>
<td><strong>Duration of follow-up</strong></td>
<td>7 months</td>
</tr>
<tr>
<td><strong>Optimisation outcome measures and results</strong></td>
<td><strong>Number (proportion) of participants with antipsychotic medication discontinuation after medication review</strong> 4/20 (20%)</td>
</tr>
<tr>
<td><strong>Author’s conclusions</strong></td>
<td>Using a survey tool with pharmacist medication review may help improve quality of prescribing of antipsychotic medications and reduce antipsychotic prescribing in people with dementia</td>
</tr>
<tr>
<td><strong>Source of funding</strong></td>
<td>Not given</td>
</tr>
<tr>
<td><strong>Quality assessment</strong></td>
<td>Fair</td>
</tr>
<tr>
<td><strong>Critical appraisal</strong></td>
<td>Selection bias Lack of blinding Small sample Lack of control group Statistical tests inappropriate or missing Lack of clinical outcomes</td>
</tr>
</tbody>
</table>

*CDPH, California Department of Public Health

<table>
<thead>
<tr>
<th>Study title</th>
<th>Impact of a psychotropic medication and physical restraint review process on adults with mental retardation, psychiatric diagnoses, and challenging behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study design</strong></td>
<td>Before-after</td>
</tr>
</tbody>
</table>

306
<table>
<thead>
<tr>
<th>Location</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>Intermediate care facility for adults with intellectual disability</td>
</tr>
<tr>
<td>Number of participants</td>
<td>n=80</td>
</tr>
</tbody>
</table>
| Participant characteristics | People with intellectual disability (22.5% mild-moderate, 77.5% severe-profound)  
Mean age (range) 34.5 (20-61) years  
75% male  
40% had axis I mental disorder |
| Intervention  | A multi-disciplinary team reviewed the use of psychotropic medication. Reviews include a standard information set including medical and medication history followed by open discussion. Recommendations are made. Cases are reviewed every six months. Review team included staff and lay members from outside the organisation. |
| Duration of follow-up | Mean 2.5 years |
| Optimisation outcome measures and results | **Total number of prescriptions for psychotropic medications**  
Reduction from 149 prescriptions at baseline to 84 prescriptions at follow-up  
**Average number of psychotropic prescriptions per person**  
Reduction from 1.86 at baseline to 1.05 at follow-up  
**Proportion of participants with change in psychotropic medications**  
47/80 (59%) changed psychotropic medication  
**Antipsychotic polypharmacy**  
Reduction from 4 (5%) participants at baseline to 0 (0%) participants at follow up  
**Reported medication side-effects**  
Side-effects reported in 11 (14%) participants at baseline and 8 (10%) participants at follow-up  
**Challenging behavior frequency counts**  
Reduction in the mean number of challenging behavior incidents per month |
| Author’s conclusions | The review process led to improvements in data gathering and documentation and reductions in the use of psychotropic medication use without accompanying increase in challenging behavior |
| Source of funding | Not given |
| Quality assessment | Fair |
| Critical appraisal | Selection bias  
Lack of blinding  
Use of unvalidated measures / non-standard assessment tools  
Statistical tests inappropriate or missing  
No control group |

**Branford, 1996**

| Study title | A review of antipsychotic drugs prescribed for people with learning disabilities who live in Leicestershire |
| Study design | Before-after |
| Location | UK |
| Setting | Hospitals, hostels, and community group homes |
| Number of participants | n=198 |
| Participant characteristics | People with intellectual disability (44% mild-moderate, 56% severe-profound)  
Mean (SD) age 43 (12.3) years  
66% male  
A minority had diagnosed mental illness |
| Intervention | Case reviews including medication history, standardized assessments of behavior (ABC) and psychopathology (Reiss |
screen and PIMRA\textsuperscript{a}), used to inform multi-disciplinary discussion (pharmacist, psychiatrist, and nursing staff). Medication decisions were made according to a flexible protocol.

**Duration of follow-up**

1 year

**Optimisation outcome measures and results**

**Proportion reducing antipsychotic medication after initial medication review**

123/198 (62\%) underwent dose reduction

**Antipsychotic dose at follow-up (those undergoing antipsychotic reduction after initial review)**

- 31/123 (25\%) discontinued antipsychotic medication
- 56/123 (46\%) reduced dose
- 27/123 (22\%) same dose
- 9/123 (7\%) higher dose

**Clinical presentation of those undergoing antipsychotic reduction after initial review**

- 31/123 (25\%) undergoing medication reduction after initial review had a “good” outcome
- 52/123 (42\%) had a “poor” outcome
- 40/123 (33\%) had “unclear” outcome

**Author’s conclusions**

Antipsychotic medication review program resulted in a withdrawal or sustained reduction in dose at 12 months in just under half those reviewed. However a relatively high proportion of case review recommendations to reduce or withdraw medication failed.

**Source of funding**

Not stated

**Quality assessment**

Fair

**Critical appraisal**

- Lack of blinding
- Use of unvalidated measures / non-standard assessment tools
- Statistical tests inappropriate or missing
- No control group
- Selective reporting / incomplete outcome data
- Lack of clinical outcomes

\textsuperscript{a}ABC, Aberrant Behavior Checklist; \textsuperscript{b}PIMRA, Psychopathology Instrument for Mentally Retarded Adults

---

**Child et al, 2012**

**Study title**

A pharmacy led program to review anti-psychotic prescribing for people with dementia

**Study design**

Before-after

**Location**

UK

**Setting**

Primary care
Participants living in care homes or in family home

**Number of participants**

\(n=70\)

**Participant characteristics**

Adults with dementia on long-term low-dose antipsychotic medications prescribed in primary care

**Intervention**

Antipsychotic medication review by a specialist pharmacist who had access to clinical and care home notes and liaised with care staff and the General Practitioner. Consensus decision reached about antipsychotic withdrawal attempts.

**Duration of follow-up**

No follow-up – outcome measured immediately after intervention

**Optimisation outcome measures and results**

**Proportion with antipsychotic medication dose reduction or discontinuation**

Antipsychotic medication withdrawn or dose reduced in 43/70 (61.4\%) cases

**Author’s conclusions**

Pharmacist-led review can successfully limit the prescribing of antipsychotics to people with dementia

**Source of funding**

Not given

**Quality assessment**

Fair
| Critical appraisal | Lack of blinding  
|                   | Statistical tests inappropriate or missing  
|                   | Missing baseline information  
|                   | Intervention varied or poorly described  
|                   | No control group  
|                   | Lack of clinical outcome measure  
|                   | Short follow-up  |

<table>
<thead>
<tr>
<th><strong>Craig et al., 1984</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study title</strong></td>
</tr>
<tr>
<td><strong>Study design</strong></td>
</tr>
<tr>
<td><strong>Location</strong></td>
</tr>
<tr>
<td><strong>Setting</strong></td>
</tr>
<tr>
<td><strong>Number of participants</strong></td>
</tr>
</tbody>
</table>
| **Participant characteristics** | Adults receiving psychotropic medication  
|                        | Further details not given |
| **Intervention**       | Two-stage review; automated (computerized) medication review to flag high doses and polypharmacy (medication exceptions) followed by a targeted review by the patient’s treating psychiatrist and clinical supervisor |
| **Duration of follow-up** | No follow-up – outcome measured immediately after intervention |
| **Optimisation outcome measures and results** | Number (proportion) of review of medication exceptions resulting in medication change  
|                                      | 67/263 (25.5%) medication exceptions identified in one year resulted in a change after clinician medication review |
| **Author’s conclusions** | An automated system is an efficient system to highlight potentially inappropriate prescribing and direct medication reviews that regularly result in corrective actions |
| **Source of funding**  | Not given |
| **Quality assessment** | Poor |
| **Critical appraisal** | Lack of blinding  
|                       | Statistical tests inappropriate or missing  
|                       | Missing baseline information  
|                       | Intervention varied or poorly described  
|                       | No control group  
|                       | Lack of clinical outcome measure  
|                       | Short follow-up  |

<table>
<thead>
<tr>
<th><strong>Dahl et al., 2008</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study title</strong></td>
</tr>
<tr>
<td><strong>Study design</strong></td>
</tr>
<tr>
<td><strong>Location</strong></td>
</tr>
<tr>
<td><strong>Setting</strong></td>
</tr>
<tr>
<td><strong>Number of participants</strong></td>
</tr>
</tbody>
</table>
| **Participant characteristics** | People with dementia (mean (SD) MMSE\textsuperscript{a} 13.5 (7.3))  
|                                  | Mean (SD) age 83.8 (7.5) years  
<p>|                                  | 74% female |
| <strong>Intervention</strong>       | Implementation of a medication review program guided by a Psychotropic Assessment Tool (PAT) to highlight psychiatric/behavioral symptoms, side-effects of psychotropic medications, and prompt patient/carer input. The PAT was completed six-monthly by a nurse, senior nurse, social worker, and family member, and discussed in interdisciplinary review meetings consisting of a pharmacist, physician, manager, and social worker. This team make recommendations for psychotropic treatment to the prescribing physician. |</p>
<table>
<thead>
<tr>
<th>Duration of follow-up</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optimisation outcome measures and results</td>
<td>Proportion of residents prescribed psychotropic medication, by type, pre- and post-intervention</td>
</tr>
<tr>
<td></td>
<td>Antipsychotics 26.5% (pre) and 25.2% (post)</td>
</tr>
<tr>
<td></td>
<td>Anti-depressants 55.8% (pre) and 55.7% (post)</td>
</tr>
<tr>
<td></td>
<td>Anxiolytics 6% (pre) and 4% (post)</td>
</tr>
<tr>
<td></td>
<td>Hypnotics 2.6% (pre) and 3.4% (post)</td>
</tr>
<tr>
<td></td>
<td>Acetylcholinesterase inhibitors 69% (pre) and 61.7% (post)</td>
</tr>
<tr>
<td></td>
<td>Memantine 51% (pre) and 52.2% (post)</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>The medication review using the PAT did not change medication use significantly but resulted in improved communication and information exchange within and between the multi-disciplinary team and families</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Not given</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Fair</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Lack of blinding</td>
</tr>
<tr>
<td></td>
<td>No control group</td>
</tr>
<tr>
<td></td>
<td>Statistical tests inappropriate or mission</td>
</tr>
<tr>
<td></td>
<td>No control group</td>
</tr>
<tr>
<td></td>
<td>Not a fixed cohort</td>
</tr>
<tr>
<td></td>
<td>Lack of clinical outcome measure</td>
</tr>
</tbody>
</table>

Donat, 2006

<table>
<thead>
<tr>
<th>Study title</th>
<th>Impact of a clinical-administrative review procedure on reducing reliance on psychotropic PRN medication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>USA</td>
</tr>
<tr>
<td>Setting</td>
<td>Psychiatric hospital</td>
</tr>
<tr>
<td>Number of participants</td>
<td>Not given</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Not given</td>
</tr>
<tr>
<td>Intervention</td>
<td>Two stage review; automated medication review to flag excessive use of PRN medication (≥ 3 uses per week) followed by targeted review by local psychologist and psychiatrist. Persistent PRN psychotropic use of ≥3 uses per week mandates senior clinician team medication review</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>12 months</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td>Average number of patients receiving ≥ 3 PRN psychotropic medications per week pre- and post-intervention</td>
</tr>
<tr>
<td></td>
<td>20.8 individuals per week exceeded PRN threshold before implementation of the medication review system, and average of 12.4 individuals after medication review implemented (statistically significant trend)</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>The medication review procedure can have a major impact on the reliance on PRN medication</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Not given</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Fair</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Lack of blinding</td>
</tr>
<tr>
<td></td>
<td>Missing baseline information</td>
</tr>
<tr>
<td></td>
<td>Intervention varied or poorly described</td>
</tr>
<tr>
<td></td>
<td>No control group</td>
</tr>
<tr>
<td></td>
<td>Lack of clinical outcome measure</td>
</tr>
<tr>
<td></td>
<td>Not a fixed cohort</td>
</tr>
</tbody>
</table>

Ellenor and Frisk, 1977

| Study title | Pharmacist impact on drug use in an institution for the mentally retarded |

*MMSE, mini mental state examination*
### Study design
Before-after

### Location
USA

### Setting
Institution for people with intellectual disability

### Number of participants
\( n = 208 \)

### Participant characteristics
Incompletely described

### Intervention
Pharmacist psychotropic medication review with recommendations to a multi-disciplinary review committee

### Duration of follow-up
Maximum 2 years

### Optimisation outcome measures and results

<table>
<thead>
<tr>
<th>Overall change in use of psychotropic medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction in number of medications from 496 pre-intervention to 313 post-intervention, from average of 2.4 to 1.5 per person</td>
</tr>
</tbody>
</table>

**Change in use of psychotropic medications, by type**

- **Antipsychotics**: 234 prescriptions pre-intervention – 83 discontinued, 101 dose reduction, 65 higher dose/initiation, 27 no change
- **Anti-depressants**: 160 prescriptions pre-intervention – 80 discontinued, 18 dose reduction, 4 higher dose/initiation, 58 no change
- **Sedative-hypnotics**: 85 prescriptions pre-intervention – 64 discontinued, 5 dose reduction, 14 higher dose/initiation, 17 no change

**Medication expenditure**

Savings related to altered medication therapies estimated at $10,000/year (1977)

**Change in challenging behaviour (measured with ABC*)**

“Slight increase” in ABC in discontinuation, dose reduction, and a comparison group not part of the medication review program, no significant difference between groups undergoing review and those not reviewed

### Author’s conclusions
Reductions in medication use possible with pharmacy and team approach, without significant clinical deteriorations

### Source of funding
Not given

### Quality assessment
Poor

### Critical appraisal
Selection bias
Lack of blinding
Statistical tests inappropriate or missing
Missing baseline information
No control group
Selective reporting / incomplete outcome data

---

*ABC. Adaptive Behavioral Scale

### Ferguson et al, 1982

<table>
<thead>
<tr>
<th>Study title</th>
<th>Effects of data-based interdisciplinary medication reviews on the prevalence and pattern of neuroleptic drug use with institutionalized mentally retarded persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>USA</td>
</tr>
<tr>
<td>Setting</td>
<td>Institution for people with intellectual disability</td>
</tr>
<tr>
<td>Number of participants</td>
<td>( n = 97 )</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>People with intellectual disability (most with severe-profound degree)</td>
</tr>
<tr>
<td></td>
<td>Age range 14 to 70 years</td>
</tr>
<tr>
<td></td>
<td>Prescribed antipsychotic medications for challenging behavior</td>
</tr>
<tr>
<td>Intervention</td>
<td>A multi-disciplinary team who met each month to review presentation and antipsychotic medication. Review included discussion of benefits and side-effects of antipsychotics. Guidelines for antipsychotic medication reduction were applied</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>Up to 18 months</td>
</tr>
</tbody>
</table>
Optimisation outcome measures and results | Number (proportion) of participants discontinuing antipsychotic medication  
Reduced from 97 before intervention to 29 after intervention (70%).

Author’s conclusions | A medication review program can play an important role in the monitoring and regulation of medication use in an institution.

Source of funding | National Institute of Mental Health

Quality assessment | Fair

Critical appraisal | Selection bias  
Lack of blinding  
Statistical tests inappropriate or missing

---

**Gallimore et al, 2016**

<table>
<thead>
<tr>
<th>Study title</th>
<th>Pharmacist medication reviews to improve safety monitoring in primary care patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>USA</td>
</tr>
<tr>
<td>Setting</td>
<td>Psychiatric out-patient clinic</td>
</tr>
<tr>
<td>Number of participants</td>
<td>n=144</td>
</tr>
</tbody>
</table>
| Participant characteristics | People accessing psychiatric out-patient care  
Mean (range) age 42.6 (11-51) years  
62% female  
Average 3.2 mental health diagnoses per patient  
73% ≥2 psychotropic medications |
| Intervention | Notes-based antipsychotic or mood stabilizer medication review by pharmacist 1-3 months after a psychiatry consultation which included review of the electronic health record for evidence of medication monitoring and potential medication interactions. Recommendations were submitted to the general practitioner |
| Duration of follow-up | 3 months |
| Optimisation outcome measures and results | Proportion with up-to-date monitoring (laboratory and other measures in accordance with national consensus guidelines)  
54.1% before medication review, 72.1% after medication review (p=0.0001)  
Proportion with up-to-date assessment of movement side-effects (AIMS) in those prescribed antipsychotic medications  
75.0% before medication review, 63.5% after medication review (p=0.2113)  
Proportion at risk of drug-drug interaction  
43.8% before medication review, 24.3% after medication review (p<0.0001) |
| Author’s conclusions | Pharmacist medication reviews are associated with significant increase in patients receiving guideline-recommended monitoring and reduction in patients at risk for drug-drug interactions |
| Source of funding | Not given |
| Quality assessment | Good |
| Critical appraisal | Selection bias  
Lack of blinding  
Lack of control group  
Lack of clinical outcome measure |

*AIMS, abnormal involuntary movement scale*
<table>
<thead>
<tr>
<th>Study title</th>
<th>Evaluating the impact of pharmacists on reducing use of sedative / hypnotics for treatment of insomnia in long-term care facility residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>USA</td>
</tr>
<tr>
<td>Setting</td>
<td>Care homes</td>
</tr>
<tr>
<td>Number of participants</td>
<td>n=34</td>
</tr>
</tbody>
</table>
| Participant characteristics | Residents of elderly care homes prescribed sedative / hypnotic medication for insomnia  
Mean (range) age 80.8 (68-94) years  
69% female |
| Intervention | Pharmacist chart review with recommendations and advice sent to prescriber (physician)                                      |
| Duration of follow-up | 3 months                                                                |
| Optimisation outcome measures and results | Number (proportion) of participants with reduction or discontinuation in sedative/hypnotic medication following review  
(At least) 16/36 (48%) participants underwent reduction or discontinuation after review |
| Author’s conclusions | Pharmacist intervention can have a meaningful impact on reducing inappropriate sedative / hypnotic use in the elderly population |
| Source of funding | No funding received                                                       |
| Quality assessment | Fair                                                                   |
| Critical appraisal | Lack of blinding  
Small sample  
Statistical tests inappropriate or missing  
Lack of control group  
Lack of clinical outcome measure  
High attrition (>20% drop out) |

Glaser & Morreau, 1986

<table>
<thead>
<tr>
<th>Study title</th>
<th>Effects of interdisciplinary team review on the use of antipsychotic agents with severely and profoundly mentally retarded persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>USA</td>
</tr>
<tr>
<td>Setting</td>
<td>Institution for people with intellectual disability</td>
</tr>
<tr>
<td>Number of participants</td>
<td>n=28</td>
</tr>
</tbody>
</table>
| Participant characteristics | People with intellectual disability (severe-profound) receiving antipsychotic medications for challenging behaviour  
71% female |
| Intervention | Monthly multi-disciplinary antipsychotic medication review meetings                                                              |
| Duration of follow-up | 6 months                                                                |
| Optimisation outcome measures and results | Number (proportion) with change to antipsychotic medication before (without) and after (with) intervention  
Greater number of participants underwent change in antipsychotic drugs occurred with the intervention (17/28) than without the intervention (11/28)  
Total dose of antipsychotic medication prescribed before (without) and after (with) intervention  
Decrease in total dose of antipsychotic dose used with intervention  
Aggressive challenging behaviour  
No difference in number of incidents of aggressive challenging behaviour in the group undergoing intervention compared with groups not undergoing intervention |
### Author’s conclusions
Multi-disciplinary medication reviews can result in reductions in the prescription of antipsychotic medications used for challenging behaviour and is not associated with worsening of aggression.

### Source of funding
Not given

### Quality assessment
Good

### Critical appraisal
Lack of blinding
Use of unvalidated measures / non-standard assessment tools
Small sample size
No control group

<table>
<thead>
<tr>
<th><strong>Inoue, 1982</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study title</strong></td>
</tr>
<tr>
<td><strong>Study design</strong></td>
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<tr>
<td><strong>Location</strong></td>
</tr>
<tr>
<td><strong>Setting</strong></td>
</tr>
<tr>
<td><strong>Number of participants</strong></td>
</tr>
<tr>
<td><strong>Participant characteristics</strong></td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
</tr>
<tr>
<td><strong>Duration of follow-up</strong></td>
</tr>
<tr>
<td><strong>Optimisation outcome measures and results</strong></td>
</tr>
<tr>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>Changes in number of psychotropic medication prescriptions before and after intervention, by type</strong></td>
</tr>
<tr>
<td>Antipsychotics: 181 prescriptions before intervention, 119 prescriptions after intervention</td>
</tr>
<tr>
<td>Anti-depressants: 22 prescriptions before intervention, 4 prescriptions after intervention</td>
</tr>
<tr>
<td>Anxiolytics: 40 prescriptions before intervention, 6 prescriptions after intervention</td>
</tr>
<tr>
<td>Sedatives / hypnotics: 27 prescriptions before intervention, 5 prescriptions after intervention</td>
</tr>
<tr>
<td>Lithium: 2 prescriptions before intervention, 3 prescriptions after intervention</td>
</tr>
<tr>
<td><strong>Number (proportion) of participants discontinuing psychotropic medication</strong></td>
</tr>
<tr>
<td>121 (48%) participants discontinued psychotropic medication following medication review intervention</td>
</tr>
<tr>
<td><strong>Clinical result of medication changes (subjective assessment)</strong></td>
</tr>
<tr>
<td>Positive change: 248/257 (96.5%)</td>
</tr>
<tr>
<td>Negative change 9/257 (3.5%)</td>
</tr>
<tr>
<td><strong>Author’s conclusions</strong></td>
</tr>
<tr>
<td><strong>Source of funding</strong></td>
</tr>
<tr>
<td><strong>Quality assessment</strong></td>
</tr>
<tr>
<td><strong>Critical appraisal</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
### Jauernig and Hudson, 1995

<table>
<thead>
<tr>
<th>Study title</th>
<th>Evaluation of an interdisciplinary review committee managing the use of psychotropic medication with people with intellectual disabilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>Australia</td>
</tr>
<tr>
<td>Setting</td>
<td>Institution for people with intellectual disability</td>
</tr>
<tr>
<td>Number of participants</td>
<td>n=25</td>
</tr>
</tbody>
</table>

**Participant characteristics**
- Incompletely reported

**Intervention**
- Multi-disciplinary team conduct medication review according to a standard structure and provided recommendations to responsible physician. Rolling process – average of 12 reviews per participant.

**Duration of follow-up**
- 2 years

**Optimisation outcome measures and results**

**Number (proportion) of participants with change to psychotropic medication**
- 19/25 (76%) reduced dose
- 3/25 (12%) discontinued
- 0/25 (0%) increased dose

**Number (proportion) of participants receiving psychotropic polypharmacy**
- Psychotropic polypharmacy: 13 (52%) before intervention, 6 (24%) at follow-up

**Change in challenging behavior (frequency counts)**
- Average daily frequency of challenging behavior lower at the end of the program than at baseline for 20/25 participants (full data not reported)

**Author’s conclusions**
- Multi-disciplinary medication review is effective in reducing use of psychotropic medication in people with intellectual disabilities in a residential setting

**Source of funding**
- Not given

**Quality assessment**
- Poor

**Critical appraisal**
- Selection bias
- Lack of blinding
- Use of unvalidated measures / non-standard assessment tools
- Small sample
- Statistical tests inappropriate or missing
- Missing baseline information

### Johnson et al, 2012

<table>
<thead>
<tr>
<th>Study title</th>
<th>Reviewing long-term anti-depressants can reduce drug burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>UK</td>
</tr>
<tr>
<td>Setting</td>
<td>Primary care</td>
</tr>
<tr>
<td>Number of participants</td>
<td>n=2,849</td>
</tr>
</tbody>
</table>

**Participant characteristics**
- Long term (≥2 year) adult users of anti-depressants, not under secondary care and without severe mental illness
- Mean (SD) age 52.4 (13.4) years
- 73.4% female

**Intervention**
- General practitioner face-to-face medication review

**Duration of follow-up**
- No follow-up – outcome measured immediately after intervention
<table>
<thead>
<tr>
<th>Optimisation outcome measures and results</th>
<th>Number (proportion) of participants with change in anti-depressant treatment after medication review</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>811 (28.5%) had any change in treatment</td>
</tr>
<tr>
<td></td>
<td>199 (7.0%) stopped anti-depressant</td>
</tr>
<tr>
<td></td>
<td>366 (12.8%) reduced anti-depressant dose</td>
</tr>
<tr>
<td></td>
<td>150 (5.3%) increased anti-depressant dose</td>
</tr>
<tr>
<td></td>
<td>96 (3.4%) switched anti-depressant medication</td>
</tr>
<tr>
<td>Group average change in anti-depressant prescribed daily dose</td>
<td>9.5% (95%CI 9.1% to 9.8%, p&lt;0.001) reduction in mean daily dose</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Author’s conclusions</th>
<th>Appropriate reductions in anti-depressant prescribing can be achieved by general practitioner review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source of funding</td>
<td>Partly by National Health Service (via incentive payments to practices undertaking medication reviews)</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Fair</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Selection bias</td>
</tr>
<tr>
<td></td>
<td>Lack of blinding</td>
</tr>
<tr>
<td></td>
<td>Missing baseline information</td>
</tr>
<tr>
<td></td>
<td>Intervention varied or poorly described</td>
</tr>
<tr>
<td></td>
<td>Lack of control group</td>
</tr>
<tr>
<td></td>
<td>Lack of clinical outcome measure</td>
</tr>
<tr>
<td></td>
<td>Short follow-up</td>
</tr>
</tbody>
</table>

**Laska et al, 1980**

<table>
<thead>
<tr>
<th>Study title</th>
<th>Automated review system for orders of psychotropic drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>USA</td>
</tr>
<tr>
<td>Setting</td>
<td>Psychiatric hospital</td>
</tr>
<tr>
<td>Number of participants</td>
<td>Not reported</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Not reported</td>
</tr>
<tr>
<td>Intervention</td>
<td>Two stage review; automated medication review to flag ‘medication exceptions’ (medication interactions or inappropriate doses) followed by clinical medication review by treating physician and clinical supervisor, and drug review committee, if necessary</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>Study period 3 years</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td>Average number of ‘medication exceptions’ (polypharmacy or dose-range exceptions) per patient over time</td>
</tr>
<tr>
<td></td>
<td>Decrease from 0.34 exceptions / patient to 0.10 exceptions / patient over study period</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>The intervention was associated with a substantial reduction in prescribing in breach of clinical guidelines</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Not given</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Fair</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Lack of blinding</td>
</tr>
<tr>
<td></td>
<td>Missing baseline information</td>
</tr>
<tr>
<td></td>
<td>Intervention varied or poorly described</td>
</tr>
<tr>
<td></td>
<td>No control group</td>
</tr>
<tr>
<td></td>
<td>Lack of clinical outcome measure</td>
</tr>
<tr>
<td></td>
<td>Not a fixed cohort</td>
</tr>
</tbody>
</table>

**Lepler et al, 1993**

<table>
<thead>
<tr>
<th>Study title</th>
<th>Implementation of an inter-disciplinary psychotropic drug review process for community-based facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>USA</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Setting</td>
<td>Community intellectual disability provider</td>
</tr>
<tr>
<td>Number of participants</td>
<td>$n=12$</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Incompletely reported</td>
</tr>
<tr>
<td>Intervention</td>
<td>Three-monthly multi-disciplinary team review of psychotropic medications on ongoing basis to discuss medication effectiveness, side-effects, and other interventions. Consensus recommendations are made and responsible physician is informed</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>Up to 4 years</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td>Number (proportion) of participants with reduced dose of psychotropic medication 9 (75%) individuals maintained on lower psychotropic dose after the intervention</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>Using a systematic method of medication review has enabled adjustments to psychotropic medication regimens leading to optimal functioning and mental health</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Not given</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Poor</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Lack of blinding, Statistical tests inappropriate or missing, Missing baseline information, No control group, Lack of clinical outcome measure</td>
</tr>
</tbody>
</table>

**Marcoux, 1985**

<table>
<thead>
<tr>
<th>Study title</th>
<th>Implementation of a psychotropic drug review service in a mental retardation facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>USA</td>
</tr>
<tr>
<td>Setting</td>
<td>Institution for people with intellectual disability</td>
</tr>
<tr>
<td>Number of participants</td>
<td>$n=255$</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Not reported</td>
</tr>
<tr>
<td>Intervention</td>
<td>Structured multi-disciplinary team review of psychotropic medication supported by standard data collection forms</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>10 months</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td>Group average change in antipsychotic medication use  Decrease of 17% in average dose of antipsychotic medications</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>The psychotropic medication review service has been successful in generating cost savings for the institution and an educational process for staff</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Not given</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Poor</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Lack of blinding, Statistical tests inappropriate or missing, Missing baseline information, Intervention varied or poorly described, No control group, Lack of clinical outcome measure, Not a fixed cohort</td>
</tr>
</tbody>
</table>

**Morrison, 2009**

<p>| Study title                  | Antipsychotic prescribing in nursing homes: an audit report                        |</p>
<table>
<thead>
<tr>
<th>Study design</th>
<th>Before-after</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>UK</td>
</tr>
<tr>
<td>Setting</td>
<td>Three nursing homes</td>
</tr>
<tr>
<td>Number of participants</td>
<td>( n=22 )</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Adults with dementia living in nursing home accommodation</td>
</tr>
<tr>
<td>Intervention</td>
<td>Application of a structured antipsychotic medication review (including rationale for prescription, assessment of side-effects, and consideration of dose reduction or discontinuation)</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>6 months</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td><strong>Number (proportion) of participants prescribed antipsychotic medications before and after medication review</strong>  Reduced from 22 (27%) at baseline to 15 (19%) at follow-up</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>The introduction of a checklist and regular medication review ensures appropriate use of antipsychotic medication in this group</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Not given</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Poor</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Lack of blinding  Small sample  Statistical tests inappropriate or missing  Missing baseline information  Lack of control group  Lack of clinical outcome measure</td>
</tr>
</tbody>
</table>

**Napolitano et al., 2012**

<table>
<thead>
<tr>
<th>Study title</th>
<th>Review clinic for people receiving anti-depressants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study design</td>
<td>Before-after</td>
</tr>
<tr>
<td>Location</td>
<td>UK</td>
</tr>
<tr>
<td>Setting</td>
<td>Primary care</td>
</tr>
<tr>
<td>Number of participants</td>
<td>( n=32 )</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>People prescribed anti-depressant medication for depression (with or without anxiety) for ≥2 years</td>
</tr>
<tr>
<td>Intervention</td>
<td>Face-to-face medication review by nurse prescriber to address medication and illness-related variables and included data from standardized scales (PHQ, GAD, WASAS, PS)</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>Unclear</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td><strong>Number (proportion) of participants with change in anti-depressant prescription following medication review</strong>  15 (47%) stopped anti-depressant medication  14 (44%) no change  3 (9%) increase dose</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>A nurse-led medication review clinic is effective in improving the quality of care and clinical outcomes</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Not given</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Poor</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Selection bias  Lack of blinding  Missing baseline information  Small sample  Statistical tests inappropriate or missing  Lack of control group  Lack of clinical outcome measure  Short follow-up</td>
</tr>
</tbody>
</table>

\(^{a}\)PHQ, patient health questionnaire; \(^{b}\)GAD, generalised anxiety disorder scale; \(^{c}\)WASAS, work and social adjustment scale; \(^{d}\)PS, phobic scale
<table>
<thead>
<tr>
<th>Study title</th>
<th>Prentice et al, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>UK</td>
</tr>
<tr>
<td>Setting</td>
<td>463 nursing homes</td>
</tr>
<tr>
<td>Number of participants</td>
<td>n=3,165</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Older adults living in nursing homes 41.1% had recorded dementia</td>
</tr>
<tr>
<td>Intervention</td>
<td>Pharmacist medication review based on NICE guidance. Reviewed symptoms (indications), side-effects, risk:benefit ratio and discussed potential for antipsychotic reduction or discontinuation with care home staff before making recommendations for prescriber (GP or psychiatrist).</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>2-4 months</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td>Number (proportion) of antipsychotic dose reductions in those undergoing review 653/3,165 (20.6%) Number (proportion) of antipsychotic medication discontinuations in those undergoing review 548/3,165 (17.3%)</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>A large reduction in antipsychotic prescribing was achieved with active intervention of community pharmacists</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Boots UK (pharmacy chain)</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Poor</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Lack of blinding Statistical tests inappropriate or missing Missing baseline information Intervention varied or poorly described Lack of control group Lack of clinical outcome measure Possible conflict of interest in funding</td>
</tr>
</tbody>
</table>

*NICE, National Institute for Health and Care Excellence

<table>
<thead>
<tr>
<th>Study title</th>
<th>Seltzer et al, 2000</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>Community</td>
</tr>
<tr>
<td>Number of participants</td>
<td>n=244</td>
</tr>
<tr>
<td>Participant characteristics</td>
<td>Age range 7-95 years (61% &gt;60 yrs) 71% female</td>
</tr>
<tr>
<td>Intervention</td>
<td>Two stage review: automated medication review to flag potentially inappropriate sedative/hypnotic prescribing (excessive dose, extended therapy, sedative / hypnotic polypharmacy) followed by letter to prescriber (physician) prompting medication review</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>12 months</td>
</tr>
<tr>
<td>Optimisation outcome measures and results</td>
<td>Number (proportion) of potentially inappropriate prescriptions stopped at follow-up 37/244 (15%) prescriptions for potentially inappropriate sedative/hypnotic agents stopped</td>
</tr>
<tr>
<td>Author’s conclusions</td>
<td>Medication review can be useful in encouraging physicians to modify prescribing practices</td>
</tr>
<tr>
<td>Source of funding</td>
<td>Not given</td>
</tr>
<tr>
<td>Quality assessment</td>
<td>Fair</td>
</tr>
<tr>
<td>Critical appraisal</td>
<td>Selection bias Lack of blinding Missing baseline information</td>
</tr>
<tr>
<td>Intervention varied or poorly described</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------</td>
<td></td>
</tr>
<tr>
<td>No control group</td>
<td></td>
</tr>
<tr>
<td>Lack of clinical outcome</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 20 Feasibility study publication in BMJ Open
### Feasibility of an online psychotropic medication review tool

**Talking about your medicines**

<table>
<thead>
<tr>
<th>![Image]</th>
<th>The Camden learning disability service is doing some research with University College London</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Image]</td>
<td>This is a new way of talking about your medicines with your doctor</td>
</tr>
<tr>
<td>![Image]</td>
<td>Someone from the Camden learning disability service will ask you if you want to hear more about the research</td>
</tr>
</tbody>
</table>

Feasibility of an online psychotropic medication review tool (IFAS 23456) – participant information leaflet v2 (22/02/2018)
<table>
<thead>
<tr>
<th>If you want to hear more they will give your contact details to the researchers</th>
</tr>
</thead>
<tbody>
<tr>
<td>The researchers will speak to you and you can decide to take part or not</td>
</tr>
<tr>
<td>You can contact us if you want to know more</td>
</tr>
<tr>
<td>You can phone us. Our phone number is [redacted]</td>
</tr>
<tr>
<td>You can e-mail us. Our e-mail is [redacted]</td>
</tr>
<tr>
<td>Thank you for looking at this leaflet</td>
</tr>
</tbody>
</table>
Appendix 22 Participant information sheet for feasibility study – participant with intellectual disability

Talking about your medicine

Participant information sheet

My name is Rory Sheehan
I work at University College London

We are doing some research
Research is when we try new things to see if they work

We are trying a new way of talking with the doctor about medicine for mental health

We would like you to take part
### What will happen if I take part?

<table>
<thead>
<tr>
<th>If you want to take part we will tell your doctor at Camden learning disability service</th>
</tr>
</thead>
<tbody>
<tr>
<td>At your appointments with the doctor they will be able to use the new system</td>
</tr>
<tr>
<td>The new system means the doctor uses a computer to help ask you questions about the good and bad things about medicine</td>
</tr>
<tr>
<td>You and the doctor can then decide what to do with the medicine</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><img src="lightbulb.png" alt="image" /></td>
</tr>
<tr>
<td><img src="man.png" alt="image" /></td>
</tr>
<tr>
<td><img src="doctor.png" alt="image" /></td>
</tr>
<tr>
<td><img src="doctor.png" alt="image" /></td>
</tr>
<tr>
<td><img src="HT.png" alt="image" /></td>
</tr>
</tbody>
</table>
What happens then?

| | University College London will keep personal information about you private on a computer that is secure for 10 years after the study has ended |
| | University College London is the data controller for this study |
| | Your right to access, move, or change information is limited because we need to make sure the information is correct |
| | We will only collect information that we need to do the research |
| | The learning disability team will only not send your name or contact details with the information you provide so that researchers will not know the information came from you |
You can find out more about how we use your data by contacting Rory Sheehan. His contact details are on the last page.

**Do I have to take part?**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Yes" /></td>
<td><img src="image" alt="No" /></td>
<td><img src="image" alt="Yes_No" /></td>
</tr>
</tbody>
</table>

You can tell us **Yes** if you want to take part.

You can tell us **No** if you do not want to take part.

If you say **no** it will not change the care that you get.
If you say yes we will ask you to sign a consent form and we will tell your doctor.

You can stop taking part at any time. In this case we will keep the information you have already given us but not collect any more information from you.

What if I have more questions?

You can ask me now.

You can phone me.
My phone number is [redacted].
You can e-mail me
My e-mail address is

This research has been looked at by the Ethics Committee. They make sure you are treated well

University College London are sponsoring the research

If you are not happy about something please tell us

Thank you for looking at this leaflet
Appendix 23 Consultee information sheet for feasibility study

LONDON'S GLOBAL UNIVERSITY

Feasibility of an online psychotropic medication review tool – research study

Invitation to take part in research

We are doing research to investigate a new way of reviewing medication for mental health (psychotropic medication) in appointments with the psychiatrist. We are studying if this new way of reviewing medication can be used in people with intellectual (learning) disability. The research has been approved by the London Bridge Research Ethics Committee. The study is being undertaken as part of a PhD degree.

Your friend or relative might be eligible to take part in this research. We feel that they are unable to decide for him/herself whether to participate in this research. To help decide if he/she should join the study, we’d like to ask your opinion whether or not they would want to be involved. This means that you will be a consultee. We’d ask you to consider what you know of their wishes and feelings, and to consider their interests. Please let us know of any advance decisions they may have made about participating in research. These should take precedence.

If you decide your friend or relative would have no objection to taking part we will ask you to read and sign a consultee declaration. We’ll then give you a copy to keep. You can let us know during the study if you have any concerns or you think your friend or relative should be withdrawn.

If you decide that your friend or relative would not wish to take part it will not affect the standard of care they receive in any way.

If you are unsure about taking the role of consultee you may seek independent advice. We will understand if you do not want to take on this responsibility.

Please read the following information about the research. You can ask us if you have any questions. If you wish to contact us our details are on the last page of this leaflet.
Information about the research for personal consultees

We would like to invite your relative or friend to take part in our research. We will listen to your opinion as someone who has an interest in their health and welfare. This information sheet will help you to understand the research and what it would involve for your friend or relative. One of our team will go through this information sheet with you and answer any questions you might have. Our contact details are at the end of this sheet.

Background to the research

Many people with intellectual disability are prescribed medication for mental health. This is also known as psychotropic medication. There has been a lot of discussion about the best way to use medication for mental health for people with intellectual disability and many people believe that its use in people with intellectual disability can be improved.

Medication for mental health (also known as psychotropic medication) can be used to treat mental illness but it might also be given in other circumstances. Psychotropic medication includes antipsychotics, anti-depressants, mood stabilisers, sleeping tablets, sedatives, and stimulants.

Intellectual disability (also known as learning disability) is a term used when a person has limitations in mental functioning and skills like communication, looking after themselves, and social skills. Some people with intellectual disability also have other conditions, like autism, mental illness, or physical health problems.

Purpose of this research

We want to help make sure that the right decisions are made about psychotropic medications. An important part of this is when people taking medications meet with the psychiatrist to talk about how the medication is working and what the pros and cons of taking it are. This is known as a medication review and is part of standard care. These meetings often involve family members or carers.

We have developed a new system that can support discussions about psychotropic medications. This is a computer programme that can help to organise the questions that the doctor asks and record the answers in a standard way. This might make it easier to make sure that all important points are covered in the review and that the information is saved in a way that makes it easier to make the right decision about medication.

Because this is a new system we need to test if it can be used in routine care. We are giving doctors at various learning disability teams access to the system. The doctor will then be able to use it in appointments where the person with intellectual disability has agreed to take part (or where it has been agreed on their behalf that they should take part). We will see how often the system is used and if it is helpful.

Who can take part in the research?

Anyone who has an intellectual disability can take part in the research if they are prescribed psychotropic medication and if they are under the care of a service that is taking part in the research. If people can make a
decision to take part for themselves they will sign a consent form. If people are not able to make a decision for themselves we seek the views of a consultee to help make a decision if they should be included or not. The consultee gives their opinion about if the person would want to take part in the research.

What does the research involve?

If you think that your friend or relative would like to take part, and if there are no other reasons why they should not take part, we will include them in the research. We will inform their General Practitioner that they are taking part.

We will tell their doctor that they are able to use the new computer system to help to review medication in your friend or relative’s appointment. It does not mean that they will see a different doctor and it does not mean that they will need any extra appointments. Their medication will be reviewed by the doctor and changes might be made if these are clinically necessary. The doctor, together with the participant and family members or carers, are still in control of medication decisions. No other aspects of your friend or relative’s care will change by them participating in the research. There will not be a researcher in the appointment.

The doctor might not use the new system for medication review. If the doctor does use the new system, information from the medication review will be stored. The doctor will also be able to keep a copy of the review so that it can be looked at again at future appointments. All of the information will be kept securely on a computer and sent to the research team to analyse. No-one else will see the information. Results will be reported at an overall level and no participant will be able to be identified from the results.

At the end of the appointment the person with intellectual disability will be asked a single question about what they thought about the medication review. This will be a simple question scored on a visual scale. The consultee does not need to be present for the appointment.

At the very end of the study we will ask the doctors who used the system for their views about how useful it was and what might need to be changed.

Where will the research take place?

The research will take place in the usual appointments that your friend or relative will have with their doctor. They might attend the clinic or the appointment might be at home. Being involved in the research will not make a difference to when and where your friend or relative is seen.

What happens after the appointment?

The participant will receive their usual care from the learning disability service and doctor. If they have further appointments during the study period (6 months) the new system may be used in these appointments, unless there is new information which would suggest they need to be excluded from the research.

There may be other opportunities to participate in research studies that follow this work. We might contact the person (or you, on behalf of the person) about these opportunities in the future. You can opt-out of any future contact if you wish.
What will happen to the information collected during the study?

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when a person agrees to take part in a research study, we use their data in the ways needed to conduct and analyse the research study. To safeguard their rights, we will use the minimum personally-identifiable information possible and we will handle this data securely.

University College London is the sponsor for this study based in the United Kingdom. We will be using information from the person enrolled in the study in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after the person's information and using it properly. University College London will keep identifiable information about the person for 10 years after the study has finished.

The participant's rights to access, change or move their information are limited, as we need to manage their information in specific ways in order for the research to be reliable and accurate. If the participant withdraws from the study, we will keep the information about them that we have already obtained. To safeguard their rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use participant's information by contacting Dr Rory Sheehan (contact details at the end of this leaflet).

The community intellectual disability team will keep the participant's name and contact details confidential and will not pass this information to University College London. The community intellectual disability team will use this information as needed, to contact the participant about the research study, and make sure that relevant information about the study is recorded for their care, and to oversee the quality of the study. Certain individuals from University College London and regulatory organisations may look at the person's medical and research records to check the accuracy of the research study. University College London will only receive information without any identifying information. The people who analyse the information will not be able to identify the participant enrolled in the study and will not be able to find out their name, NHS number or contact details.

The community intellectual disability team will keep identifiable information about participants collected for this study until the study has finished which is a maximum of six months after a participant is enrolled in the study.

What are the possible advantages of taking part?

The new system of medication review might provide benefit to participants. The aim of the new system is to facilitate a comprehensive review of medication that will cover important points and make it easier to make the right decision about medication treatment. Another advantage of the system is that it records information in a simple and consistent way that can be used over time to track medication effects.

Participating in this research will help us to develop the medication review system. We know that getting medication decisions right is important to people with intellectual disability and those who support them. Participants might be satisfied to know that their involvement in this study can lead to better understanding and improvements in this important area.
What are the possible disadvantages of taking part?

There are few risks to participants. Medication review is part of standard care. The new system is a different way of organising the medication review. The doctor will lead the review and if they feel it is not appropriate to use the new system in the appointment they will not be obliged to use it. If some questions in the new system are not relevant they can be missed out. The new system does not mean that changes will necessarily be made to medication. Any medication changes will be decided on by the doctor and the patient (and family member or carer, where applicable).

We will keep all information secure and personal data will be handled in accordance with data protection regulations.

Does my friend or relative have to be involved?

No. If you do not think your friend or relative would like to be involved in this research please tell us and we will not include them. This decision will not affect the care that they receive.

Withdrawing from the study

If at any point in the study you feel that your friend or relative would no longer like to be involved, please let us know and they can withdraw from the study. This decision will not affect the care that they receive. You can contact us at any point to ask about the research. If a person is withdrawn from the study the data they have contributed will be kept but no further data will be collected.

Who is organising and funding this study?

This study is organised by researchers at University College London (UCL). The study is funded by the National Institute for Health Research (NIHR) which is the research arm of the NHS.

The medication review system that will be used has been developed by a company (HealthTracker™) which one of the members of the research team has a shareholding in.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect the interests of participants. This study has been reviewed and given a favourable opinion by London Bridge Research Ethics Committee. University College London have also reviewed this study and are sponsoring the research.

What if there is a problem?

If you have any concerns about this research you can speak to Rory Sheehan (e-mail [redacted] or telephone [redacted]) who will do his best to help you.

In the unlikely event that a participant is harmed by taking part in this research and you suspect this is due to negligence then you may be able to claim compensation. Claims should be made in writing and sent to Professor
Angela Hassiotis (e-mail [redacted] or telephone [redacted]) who is the Chief Investigator for the study.

Thank you for taking the time to read this leaflet

Please contact us if you have any questions or would like to be involved. The Chief investigator for this study is Professor Angela Hassiotis and the Principal Investigator is Dr Rory Sheehan.

Contact details of research team

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<th>Name</th>
<th>Address</th>
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<tr>
<td>Rory Sheehan</td>
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<td>Professor Angela Hassiotis</td>
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Feasibility of an online psychotropic medication review tool

*Talking about your medicines*

Participant consent form

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<td><img src="image1.png" alt="Image" /> I have read the</td>
<td><img src="image2.png" alt="Image" /> X</td>
<td><img src="image3.png" alt="Image" /> ✓</td>
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<td>information sheet about the research</td>
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<td><img src="image4.png" alt="Image" /> I can understand the</td>
<td><img src="image5.png" alt="Image" /> X</td>
<td><img src="image6.png" alt="Image" /> ✓</td>
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<td>information sheet</td>
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<td><img src="image7.png" alt="Image" /> I could ask questions</td>
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<td>I understand that it is my choice to take part</td>
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<td>I understand that I can say <strong>no</strong> at any time if I want to stop</td>
<td><strong>✓</strong></td>
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<td>I understand that I can say no to taking part and this will not affect my care</td>
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<td>You can tell my doctor I would like to take part</td>
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<td>![Image] <a href="#">I am happy for the doctor to use the new system to talk about my medicine</a></td>
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<td>![Image] <a href="#">I understand information about me will be saved on a secure computer</a></td>
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<td>![Image] <a href="#">I would like to hear about more research in the future (optional)</a></td>
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Feasibility of an online psychotropic medication review tool (IRAS 24800) – participant consent form v3 | 10/07/18
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Appendix 25 Consultee declaration form for feasibility study

Feasibility of an online psychotropic medication review tool – research study

Personal consultee declaration

Participant Name: ..............................................

Please initial the box to indicate you agree with each statement

I confirm that I have agreed to act as a consultee for the above named person. I understand that my role as a consultee is to advise the research team as to the above named persons’ likely wishes and feelings in relation to taking part in the study

I confirm that I have read and understood the study information sheet. I have had the opportunity to discuss the research and ask questions

In my opinion my friend or relative named above would have no objection to taking part in this study

I understand that participation is voluntary and saying no will not affect the care of the person. I understand that I can request the person is withdrawn from the study at any time without giving a reason and without his/her care being affected

I understand that participant’s personal information will be held securely for the purposes of conducting this study

I understand that if the person takes part in this study their General Practitioner will be informed
I agree for the research team to contact me as a possible consultee in the future about related studies (optional)

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Appendix 26 Participant with intellectual disability feedback question

how able were you to say everything you wanted to say about medicine today? Was it...

very difficult  difficult  not easy or difficult  easy  very easy
Appendix 27 Online feedback questionnaire for psychiatrists who took part in the feasibility study

HealthTracker feasibility study - clinician feedback

Dear Colleague,

We would like to invite you to give feedback on your involvement as a clinician researcher in the HealthTracker feasibility study.

The feasibility study tested a new method of medication review called HealthTracker in a group of adults with intellectual disability. The HealthTracker system is designed to be used in routine clinical appointments to structure and organise medication reviews and to aid the medication decision-making process.

We would like to hear from clinicians who have been involved in the project. We are interested in the recruitment process (part 1 of the questionnaire) and your experiences of using the HealthTracker system (part 2). This online questionnaire consists of 12 questions in total and will take approximately 15 minutes to complete. You can take this questionnaire even if you did not use the HealthTracker system, in which case you will be directed only to relevant questions.

We will collate responses to the questionnaire and report these at aggregate level. We may also report short quotations from your answers but these will not be attributed to you as individuals and we will not collect any personally-identifiable information. We hope that the understanding gained from this work will help in future research with people with intellectual disability and inform modifications to the HealthTracker system that might improve its utility.

This study is organised by researchers at University College London and is funded by the National Institute for Health Research (NIHR).

If you have any further questions about the research or this questionnaire please contact Rory Sheehan (e-mail [redacted] or telephone [redacted]).
HealthTracker feasibility study - clinician feedback

1. How easy was it to introduce the HealthTracker study to potential participants?
   - Very difficult
   - Difficult
   - Not easy or difficult
   - Easy
   - Very easy

2. Did you encounter any barriers in introducing the research to potential participants? If so, please explain these in the box.
   - I did not encounter any barriers in introducing the research
   - I did encounter barriers in introducing the research (please explain)

3. In cases where people did not want to hear more about the research, did they give a reason? Tick all that apply and explain ‘other reasons’ in the box.
   - No reason given
   - Already taking part in research
   - Worried about inconvenience or commitment
   - Did not want to discuss or change medication
   - Did not understand what they were being asked to do
   - Fear of research procedures or adverse effects of research
   - Concern about confidentiality
   - Carer did not think research was appropriate
   - For those who lacked capacity, the carer was not willing to act as consultee
   - Other reasons why people did not want to hear more about the research (please give detail)

4. Did you use the HealthTracker system?
   - Yes
   - No
Using the HealthTracker system

5. How easy was it to use the HealthTracker?

- Very difficult
- Difficult
- Not easy or difficult
- Easy
- Very easy

6. Did you experience any barriers to using the HealthTracker for medication review? Tick all that apply and describe 'other barriers' in the box.

- No barriers
- Patient did not attend appointment in which HealthTracker was to be used
- Lack of access to computer or internet
- HealthTracker practicalities were difficult (e.g., logging in, registering patients)
- Using the computer interrupted interaction with patient or carer
- It was difficult to gather the necessary information to complete the HealthTracker
- Using the HealthTracker took too long
- Other barriers (please explain)

7. Did using the HealthTracker help the person with intellectual disability and/or their carer to be more involved in the medication review? Please make additional comments in the box.

- Yes
- No

8. Did using the HealthTracker help you to make a decision about changing, stopping or continuing medication? Please use the text box to expand on your answer.

- Yes
- No
9. Did using the HealthTracker make it more likely you would change medication compared with your usual practice? Please make any additional comments in the box.
   - Yes
   - No

10. Did using the HealthTracker change the consultation in any way? Please use the text box for comments.
    - Yes
    - No

11. Do you think that the HealthTracker system should be used more widely? Please explain your answer in the free text box and include any suggestions you have for changes to the HealthTracker.
    - Yes
    - No

12. Please use this space for anything else you would like to say about this research or the HealthTracker system.
Appendix 28 Ethics approval for feasibility study – participant with intellectual disability

Dear Professor Hassiotis

Study title: An online tool (HealthTrackerTM) to support psychotropic medication review for people with intellectual disability: feasibility study in community psychiatry of intellectual disability teams

IRAS project ID: 244666
Protocol number: 18/0220
REC reference: 18/LO/1112
Sponsor University College London

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales? You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Following the arranging of capacity and capability, participating NHS organisations should formally confirm their capacity and capability to undertake the study. How this will be confirmed is detailed in the “summary of assessment” section towards the end of this letter.

You should provide, if you have not already done so, detailed instructions to each organisation as to how you will notify them that research activities may commence at site following their confirmation of capacity and capability (e.g. provision by you of a ‘green light’ email, formal notification following a site initiation visit, activities may commence immediately following confirmation by participating organisation, etc.)
It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any national specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document “After Ethical Review – guidance for sponsors and investigators”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:
- Registration of research
- Notifying amendments
- Notifying the end of the study
The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Misha Ladv
Tel: 
Email: 

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is 244866. Please quote this on all correspondence.
Yours sincerely

Chris Kitchen
Assessor

Email: hra.approval@nhs.net

Copy to: Misha Ladva, University College London (Sponsor Contact)
Mc Lynis Lewis, NOCLOR (R&D Contact)