
**Translating Evidence into Practice:
Behavioural Support for Smoking Cessation**

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Declaration

The following work was carried out at the Centre for Outcomes Research and Effectiveness, in the Department of Clinical, Educational, and Health Psychology, University College London, under the supervision of Professor Susan Michie and Professor Robert West. Chapter 2, with amendments, has been published (Lorenцatto, West, & Michie, 2012); Chapter 3, with amendments, has been published (Lorenцatto, West, & Michie, 2013); Chapter 4, with amendments, has been published (Lorenцatto, Seymour, West, & Michie, 2013); Chapter 5, with amendments, has been published (Lorenцatto, Christopherson, West, & Michie, 2013); Chapter 6, with amendments is under review for publication (Lorenцatto, Bruguera, West, & Michie, under review). See Appendix 11 for copies of the papers that have been published. The results from Chapters 2-7 have also been presented at the British Psychological Society’s Division of Health Psychology Conference (2010, 2012, 2013), The UK National Smoking Cessation Conference (2011, 2012, 2013), The European Health Psychology Society Conference (2011), The UK Society of Behavioural Medicine Conference (2011, 2012), and The Society for Research in Nicotine and Tobacco Conference (2012).

This thesis is my own work and contains nothing which is the outcome of work done in collaboration with others, except as specified above, where co-authors have been noted. Any auxiliary support is noted in the acknowledgements. My work was supported by the National Centre for Smoking Cessation and Training, funded by the Department of Health. Correspondence concerning this thesis should be addressed to Fabiana Lorenцatto, fabilorenцatto@gmail.com.

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Abstract

Background: Evidence-based behaviour change interventions are increasingly implemented in wider clinical practice, such as smoking cessation behavioural support interventions (BSIs) delivered via the English NHS Stop Smoking Services (SSSs). However, the process of translating evidence into practice is complex, slow and often unpredictable.

Aims: This thesis investigated factors related to the translation of evidence into practice for smoking cessation BSIs, including: specification and reporting of intervention components, fidelity and quality of delivery, and associations between implementation and outcome.

Methods: Six mixed-methods studies were conducted using BSIs delivered by the NHS SSSs as a case study for examining implementation. In Study 1, a taxonomy of smoking cessation behaviour change techniques (BCTs) was applied to specify components comprising effective BSIs for pregnant smokers. Study 2 applied the taxonomy to assess the current standard of published reporting of the content of BSIs. Study 3 assessed the reliability of the taxonomy as a framework for specifying BCTs in transcripts of audio-recorded behavioural support sessions. Studies 4 and 5 applied the taxonomy to assess the extent to which manual-specified BCTs are delivered in practice (i.e. fidelity). Study 6 developed a 10-point scale for rating quality of delivery of a key BCT ‘goal-setting,’ and examined whether quality was associated with smokers’ enactment of planned quit attempts (i.e. outcome).

Results: The taxonomy demonstrated consistently high reliability for coding into component BCTs the content of BSIs as described in published reports, trial protocols, service treatment manuals and session transcripts, (Studies 1-5). Using this method, 11 evidence-based BCTs for smoking cessation in pregnancy were specified (Study 1). Published reports of BSIs were inadequate, omitting on average 50% of intervention content originally specified in trial

protocols (Study 2). Fidelity was found to be consistently low, with typically less than 50% of manual-specified content being delivered (Studies 4 and 5). It was possible to reliably assess quality of ‘goal-setting,’ which on average was low; however, higher quality of goal-setting significantly increased the likelihood of smokers enacting planned quit attempts (Study 6).

Conclusions: Translation of evidence into practice for smoking cessation BSIs is not uniform, with information loss occurring as interventions are disseminated and delivered in practice. The taxonomy provides a reliable methodological approach for examining factors related to implementation. Observed translational issues may inform future training and interventions to improve implementation of BSIs in clinical practice.

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Pre-face: Brief summary of thesis

Evidence continues to emerge illustrating the potential effectiveness and cost-effectiveness of interventions to change health related behaviour. An increasing number of these interventions have in turn been implemented as part of wider clinical practice. However, the outcomes of complex behaviour change interventions in both research and practice are often variable (NICE, 2007). The translation of evidence-based findings into the context of clinical practice is typically slow, haphazard and variable (Eccles, Armstrong, et al., 2009). Behavioural support interventions for smoking cessation have demonstrated effectiveness in evaluative trials (Lancaster & Stead, 2005a), and have been widely implemented in practice in the UK via the English NHS Stop Smoking Services, with substantial observed variability in quit outcomes across services (NHS Information Centre, 2011). This thesis examines factors related to the implementation of complex evidence-based interventions in clinical practice, using smoking cessation behavioural support delivered by these NHS services as a case study. The behaviour of groups responsible for translating evidence into practice was examined, including researchers reporting intervention content in published reports, healthcare professionals delivering interventions, and smokers receiving and subsequently enacting interventions. The thesis comprises six studies using a recently developed taxonomy of smoking cessation behaviour change techniques to: (i) systematically evaluate the current specification and reporting of smoking cessation behavioural support interventions, (ii) develop methods for assessing the fidelity and quality with which these interventions were delivered, and (iii) examine the extent to which quality of delivery relates to intervention enactment by intervention recipients.

CHAPTER 1: General Introduction

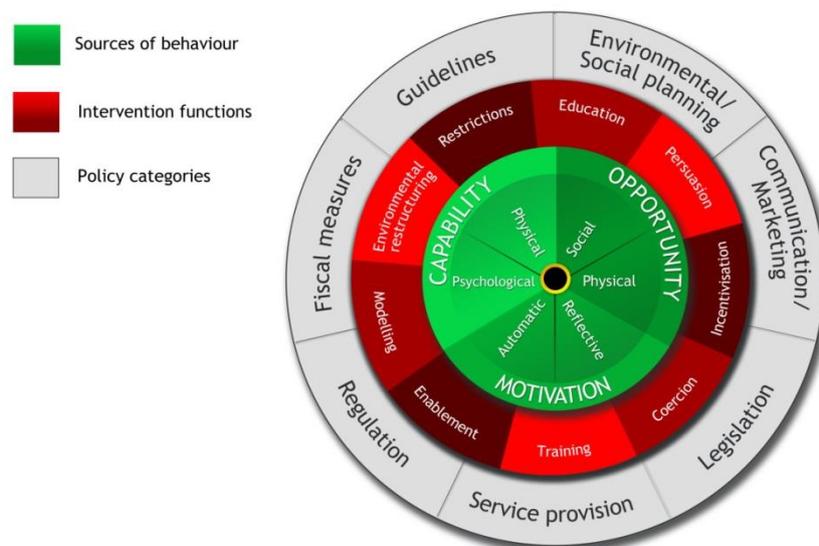
1.1. Interventions to Improve Health

Emerging evidence continues to highlight the role of behaviour in explaining many of the leading current health and healthcare issues. For instance, 2.4 million deaths in the United States in 2000 were linked to health behaviours such as smoking, diet, physical activity, and alcohol consumption (Mokdad, Marks, Stroup, & Gerberding, 2004). It is therefore increasingly recognised that improving health and related outcomes requires changing patterns in health-related behaviours. This is reflected by the growing investment into developing and evaluating interventions to change behaviour (Michie, Abraham, et al., 2011).

Health psychology and behavioural medicine have played instrumental roles in developing and evaluating numerous types of behaviour change interventions. Interventions developed to date have targeted behaviour change at various levels, from individual to group, organisational, community and population (NICE, 2007). For example, interventions may be preventive and focus on changing behaviours in healthy individuals (e.g. smoking cessation, increasing physical activity and healthy eating), or in those who are ill in order to improve adjustment to illness and prevent deterioration (e.g. promoting medication adherence). Further, clinical practice is a form of human behaviour (Foy, Francis, et al., 2007), and interventions may thus be aimed at changing the behaviour of health professionals tasked with delivering effective and evidence-based healthcare (Michie, Fixsen, Grimshaw, & Eccles, 2009). Behaviour change interventions have been delivered through numerous modalities such as face-to-face individual- and group-based sessions, telephone, self-help materials, or population-level, mass media, public health campaigns. With increasing developments in technology, a rising number of interventions are also being delivered via the internet, SMS text messaging, and smart phone applications (Fjeldsoe, Marshall, & Miller, 2009; Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004). The target behavioural outcome may aim to *increase* the performance of a desired behaviour, such as increasing

attendance to cancer screening (Sadler, Albrow, Shelton, Kitchener, & Brabin, 2012) or promoting adherence to clinical guidelines by healthcare providers, such as improving hand hygiene in hospitals (Pittet et al., 2000). Conversely, the behavioural outcome may be a *decrease* in the performance of behaviour, such as promoting smoking cessation (Lancaster & Stead, 2005) or reducing health professionals’ requests for unnecessary x-rays for acute lower back pain (McKenzie et al., 2008). Interventions may aim to achieve these target outcomes through a range of behaviour change functions, such as persuasion, enablement, and modelling. A comprehensive set of behaviour change functions are outlined in the recently developed ‘Behaviour Change Wheel’ (Figure 1) (Michie, van Stralen, & West, 2011).

Figure 1. The Behaviour Change Wheel (Michie, van Stralen, & West, 2011)



Evaluation trials of these diverse behaviour change interventions conducted in the context of clinical and health services research continue to produce findings with the potential to promote more effective, efficient and safe patient care (Foy, Francis, et al., 2007; Grimshaw et al., 2006). Numerous Cochrane reviews provide a synthesis of the existing evidence for interventions aimed at promoting health, and demonstrate that health behaviour change

interventions are both effective and potentially cost-effective across a range of domains (see: www.thecochranelibrary.com). However, there is considerable heterogeneity in the outcomes of behaviour change interventions (NICE, 2007), highlighting the need to examine factors contributing to this variability.

1.2. Translating evidence-based interventions into practice: Implementation Research

As evidence for the effectiveness of these behaviour change interventions accumulates, an increasing number of interventions are being implemented on a large scale in clinical practice with the aim of obtaining widespread health benefits at the population level. This reflects the growing movement towards evidence-based healthcare, which has increased in prominence over recent years (Rosenfeld, Shiffman, & Robertson, 2013). It has long been recognised that routine clinical practice should be informed by scientific evidence (Chilvers, Harrison, Sipos, & Barley, 2002). The primary goal of evidence-based healthcare is to improve patient outcomes and quality of care. This is achieved by explicitly and judiciously basing public health decision making and delivered healthcare on the current best available research evidence and scientific knowledge, rather than on existing customary practice or the personal beliefs of healthcare providers (Des Jarlais, Lyles, & Crepaz, 2004). This process typically involves examining research findings to identify interventions for which there is accepted evidence of clinical efficacy and effectiveness, and using these findings as a basis for developing evidence-based recommendations to inform clinical practice (Davidson et al., 2003). Not only does evidence-based healthcare help link healthcare with the best available scientific data, but it also guides quality improvement efforts and outlines criteria for decision making in the allocation of healthcare resources (Rosenfeld et al., 2013).

Investigating how evidence-based interventions are translated into clinical practice is part of an emerging discipline referred to as implementation research. Implementation research is defined as: ‘the scientific study of methods to promote the systematic uptake of clinical

research findings and other evidence-based practices into routine clinical practice and hence to improve the effectiveness, reliability, safety, appropriateness, equity and efficiency of healthcare’ (Eccles et al., 2009). More simply, implementation concerns how *well* a proposed, evidence-based program or intervention is put into practice. Implementation research also involves examination of influences on healthcare professional behaviours and methods to enable them to use research findings more effectively in practice (Durlak, 1998).

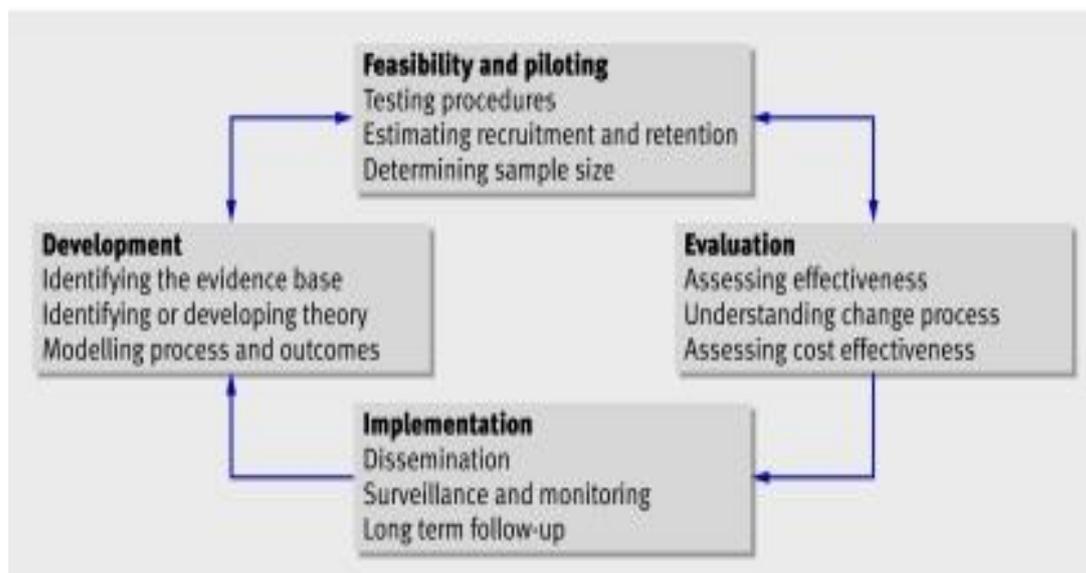
1.3. The ‘Ideal’ Implementation Process

In order for interventions with demonstrated effectiveness to achieve desired health benefits in practice, these interventions must be adopted and implemented consistently by relevant healthcare professionals, systems, and organisations (Eccles, Armstrong, et al., 2009; Penney & Foy, 2007). The transfer of new scientific knowledge (i.e. evidence) into clinical practice is a dynamic and iterative process, involving numerous stages of information transfer. This process is embedded within a complex system of interactions between researchers, policy makers, guideline developers, healthcare service managers, commissioners and health care professionals (Grimshaw et al., 2001).

The first step in the implementation process concerns developing evidence through primary research studies. In the UK, the Medical Research Council (MRC) has published an influential framework that outlines the phases involved in developing and evaluating complex interventions (Craig et al., 2008; MRC, 2000), drawing parallels with those phases involved in drug development. According to the original MRC framework, best practice is to systematically develop an intervention by using existing evidence and theory to establish an appropriate rationale for the intervention and to specify the intervention components. Once the intervention is developed, the intervention processes and outcomes should be modelled and carefully tested in a phased approach, beginning with a series of exploratory pilot studies to assess the feasibility of the intervention. The pilot studies should be aimed at areas of

uncertainty in the intervention design, and inform subsequent refinements and further developments of the intervention as needed. Following this, the intervention should be formally evaluated in a definitive evaluation study, preferably a randomized controlled trial (RCT) or cluster-RCT. Findings from the evaluative trial will provide evidence of the interventions effectiveness or ineffectiveness. This original MRC framework proposed a linear, sequential process. It has since been revised to represent a cyclical process, in recognition of the fact that implementation should be considered both at the beginning of this process and throughout, as implementation is central to all stages of intervention development and evaluation (Craig et al., 2008) (Figure 2).

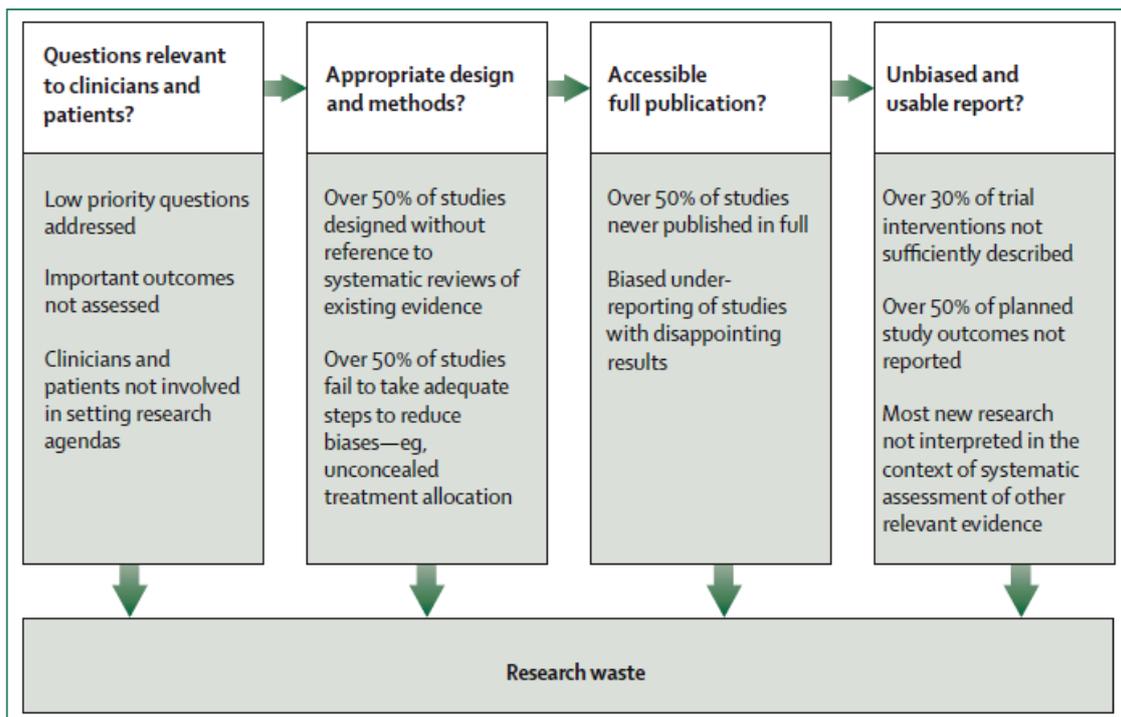
Figure. 2. Key elements of the revised Medical Research Council framework for developing and evaluating complex interventions (Craig et al., 2008)



If evidence is to potentially influence practice, it has to be made available. Therefore, once it has been established that an intervention is effective, this finding should be disseminated as widely as possible (Craig et al., 2008). This requires clear and consistent communication as to what constituted the original evidence-based intervention (Des Jarlais et al., 2004). The

dissemination of emerging scientific knowledge is primarily achieved through the publication of research findings in peer-reviewed journals (Grimshaw & Eccles, 2004). Comprehensive descriptions of intervention content should be made readily accessible in an unbiased and usable published intervention report; failure to do so is one potential factor leading to the avoidable waste of research evidence (Chalmers & Glasziou, 2009) (Figure 3).

Figure 3. Stages of waste in the production and reporting of research evidence relevant to clinicians and patients (Chalmers & Glasziou, 2009).



Several guidelines have been published that are aimed at improving and facilitating the reporting of interventions and related results in published journal reports. The well-established ‘Consolidated Standard of Reporting Trials’ (CONSORT) statement (Altman et al., 2001; Moher, Schulz, & Altman, 2001) provides a set of guidelines for comprehensively and transparently reporting the ‘precise details of interventions as actually administered.’ It

comprises a 22-item checklist of items that should be described in detail in published reports. These range from the initial scientific background, rationale and hypotheses for the trial, through to the eligibility criteria, participant randomization and blinding procedures, intervention content, statistical analysis methods, outcomes, generalizability of findings, etc. (Altman et al., 2001). The original CONSORT statement was intended for randomized controlled trials (RCTs) of all types of clinical interventions, regardless of their purpose (Davidson et al., 2003). It has since been extended to address other types of intervention designs, such as RCTs of non-pharmacological treatments (Boutron, Moher, Altman, Schulz, & Ravaud, 2008), of non-randomized designs (i.e. TREND statement) (Des Jarlais et al., 2004), observational studies (von Elm et al., 2008), non-inferiority and equivalence trials (Piaggio, Elbourne, Pocock, Evans, & Altman, 2012), and systematic reviews and meta-analyses (i.e. PRISMA) (Moher, 2010; Moher, Liberati, Tetzlaff, & Altman, 2010). An extension of CONSORT for reporting interventions in the domain of evidence-based healthcare lists eight components of interventions that should feature in trial evaluation reports and manuals, which are: 1) the content/elements of the intervention, 2) characteristics of intervention providers, 3) characteristics of intervention recipients, 4) setting (e.g. worksite), 5) mode of delivery (e.g. face-to-face), 6) intensity (e.g. contact time), 7) duration (e.g. number of sessions), and 8) adherence to protocols (Davidson et al., 2003). This information should be reported in sufficient detail to allow accurate replication (Abraham & Michie, 2008; Davidson et al., 2003).

By using these guidelines when preparing intervention reports, intervention descriptions are likely to be more comprehensive, transparent and consistent. This level of reporting will enable readers involved in designing, evaluating or reviewing interventions (i.e. guideline developers, policy makers, clinicians, researchers) to be informed as to exactly ‘what’ comprised the original intervention, and hence to replicate the intervention faithfully,

synthesise findings, and identify sources of bias threatening the validity of findings (Davidson et al., 2003). In turn, this should facilitate and accelerate the application of evidence-based findings in clinical practice, whilst minimising potential for information loss and inconsistency across the sequential stages of the implementation process.

Translation of evidence into practice may be done directly, by healthcare providers accessing findings from published reports or systematic reviews. However, there are many intermediate routes to bridging research and practice, one of which is through clinical guidelines. Clinical guidelines are increasingly being used to establish a consistent standard for higher-quality of evidence-based healthcare (Penney & Foy, 2007). Clinical guidelines are statements that outline recommendations for practice that are based on an examination of the currently best available evidence and an assessment of the potential benefits and harms of alternative healthcare options or interventions (Rosenfeld et al., 2013). The overarching aim of guidelines is to optimise patient care, particularly in areas of healthcare where substantial variation in provision exists. This is achieved by using guidelines to inform best practice, provide a framework for clinical decision making, evaluating performance, promoting consistency of care and discouraging ineffective or potentially harmful interventions (Rosenfeld et al., 2013). Developing clinical guidelines is a complex, multi-stage and sequential process. It begins by establishing the current relevant base evidence-base, typically through systematically reviewing the relevant literature. This evidence is then used to inform the development of evidence-based guidelines that outline clear and unambiguous actionable recommendations to inform healthcare providers, and other relevant bodies, as to precisely what to do, to whom, under which specific circumstances (Rosenfeld et al., 2013).

The aim is for these actionable recommendations to filter down to the clinical practice level either by influencing clinical practice directly, or indirectly by informing the content of treatment manuals or relevant healthcare provider training. The term ‘treatment manual’

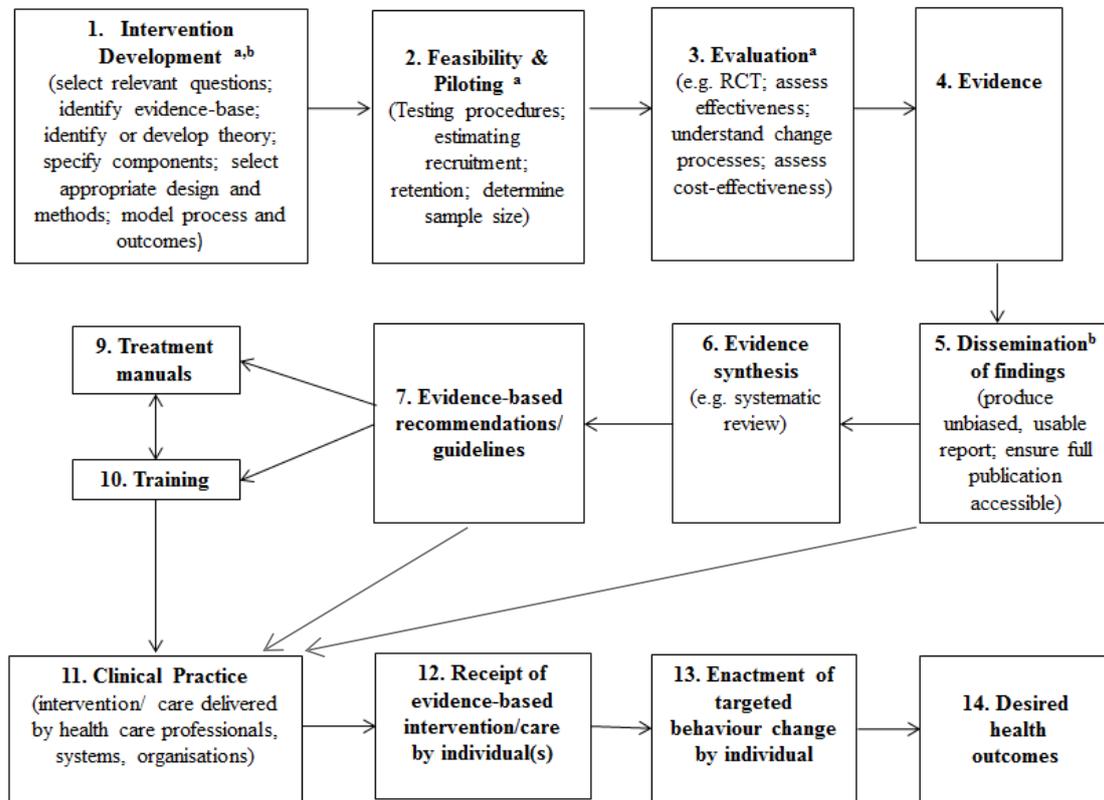
typically refers to structured, procedural books outlining the rationale and goals of an intervention, as well as the recommended content to be delivered when administering an intervention (Wilson, 1996). Use of manuals in practice confers many benefits from an implementation perspective. Manuals promote consistency and help focus and shape the content of typically time-limited delivered healthcare. If the content of treatment manuals is based on systematic reviews of relevant literature or on evidence-based clinical guidelines, they potentially provide a platform by which findings from effective evaluative trials may be translated into practice (Wilson, 1996). There is also an increasing trend towards using evidence-based findings to specify the competences (i.e. core knowledge and skills) required by healthcare providers, and ensuring these competences feature in relevant certification and update training programmes, as well as continuing professional development courses or medical education programs (Muse & McManus, 2013). A framework of competences for delivering cognitive behavioural therapy has systematically been developed using an evidence-based, methodological approach (Roth & Pilling, 2008). Moreover, in England, the National Centre for Smoking Cessation and Training (see: www.ncsct.co.uk) conducted research to identify the evidence-based competences required to deliver smoking cessation behavioural support prior to developing a national online training and certification program on the basis of these findings in order to ensure a standard of competence for specialist Stop Smoking Practitioners in the delivery of evidence-based behavioural support (Brose, West, Michie, Kenyon, & McEwen, 2012).

A combination of clinical guidelines, treatment manuals and competence-based training provides different routes through which evidence-based findings may influence the behaviour of healthcare providers and result in the delivery of evidence-based clinical practice. The ultimate aim is for clients/patients to receive evidence-based healthcare. Usually the care or intervention delivered requires behaviour change by the recipient, for example, by adhering

to medication use or quitting smoking; the evidence-based intervention should therefore prompt enactment of the desired behaviour change by the recipient in order for the desired health benefits and outcomes to ultimately be achieved.

These stages of translating research into practice can be combined in a unitary model to illustrate this sequential process (Figure 4). This model, comprising 14 steps, incorporates both the MRC framework's guidance for designing and evaluating complex interventions (Steps 1 to 4, Figure 4) and Chalmers and Glasziou's recommendations for disseminating findings in an appropriate and accessible manner (Step 4-5) (Chalmers & Glasziou, 2009). The behaviour of several different groups of individuals feature, including: researchers responsible for designing, evaluating and disseminating evidence relating to behaviour change interventions (Steps 1-6), those involved in policy making, guideline and training development (steps 6-10), healthcare professionals tasked with delivering interventions in clinical practice (step 11), and intervention recipients responsible for enacting delivered interventions (Step 12-13). In order to increase the likelihood of health outcomes being achieved (Step 14), it is necessary to continuously monitor whether the components of interventions are being implemented consistently and faithfully throughout dissemination and practice stages by these different groups of individuals, or whether there is translational loss or alteration of intervention components along the way.

Figure 4. Stages involved in translating evidence-based interventions into practice.



^a=based on MRC guidance (Craig et al. 2008)
^b based on Chalmers & Glasziou (2009)

1.4. Examining implementation of health behaviour change interventions

For some forms of healthcare or specific types of interventions, the progression from translating new research findings along this implementation chain into clinical practice will be straightforward. For example, when evidence emerged that a more conservative treatment for children with acute otitis media was as equally effective as a more aggressive treatment, myringotomy, the dissemination of this finding in a medical journal was sufficient for nearly all relevant doctors to cease performing the more aggressive procedure within a short period of time (Grol & Grimshaw, 2003; van Weel, Gouma, & Lamberts, 2003).

However, the step from ‘best evidence’ to ‘best practice’ will not always be so systematic or direct. Nor will the progression through the distinct stages of the implementation process. Although it may be helpful to think of the process of translating evidence into practice as an ‘ideal’ sequence of stages progressively building upon the previous, the reality is that in the context of clinical practice, this ideal is rarely achieved. The implementation process will rarely be linear but rather cyclical, as depicted in the revised MRC framework (Campbell et al., 2007; Craig et al., 2008) (Figure 2). Implementation can exist in degrees along a continuum from all (100%) to none (0%), and it is acknowledged that some variation in how programs are delivered when implemented in different or new settings is likely if not inevitable (Elias, 1997). The translation of research findings into practice is therefore rarely a uniform process, but instead an unpredictable, slow, and often haphazard one (Eccles et al., 2007).

This is particularly true for complex interventions aiming to change health-related behaviours. These interventions are complex in that they comprise multiple, often interacting, components. Components include behaviour change techniques (BCTs) representing the ‘active ingredients’ of the intervention, as well as the procedures for delivering these BCTs (i.e. who/whom/how often/format/context) (Michie, Abraham, Whittington, McAteer, & Gupta, 2009). The number of experimental and control conditions, levels targeted, outcomes examined also contribute to the complexity of interventions. Complex interventions are widely used in health services, public health practice, and areas of social policy which bear important consequences for health (Craig et al., 2008). Few interventions are genuinely ‘simple,’ with most interventions encompassing some degree of complexity, and some highly complex interventions, such as cognitive behavioural therapy, comprising multiple ‘sub-interventions’ which are classifiable as complex in their own right (Craig et al., 2008; Roth & Pilling, 2008). Given such complexity, substantial difficulties are often encountered when

trying to evaluate the effects of health behaviour change interventions or assess their implementation in practice (Grol & Grimshaw, 2003).

Such challenges are magnified by the fact that complex behaviour change interventions are often context-dependent. Many of the contexts in which these interventions are delivered, such as healthcare settings, are typically dynamic, unpredictable, and therefore difficult to control (Montgomery et al., 2013). Many of the processes and functions involved in these interventions may require a degree of tailoring specific to the context or individual recipient whilst still aiming to achieve the same outcomes (Bonell, Fletcher, Morton, Lorenc, & Moore, 2012). Furthermore, in practice and community settings, complex behaviour change interventions may be delivered across multiple sites, by multiple healthcare professionals, to a range of recipients (Durlak, 1998). Ensuring standards and consistency in implementation in such contexts is more challenging than in a single-setting. Indeed, there is evidence that the risk of an intervention deviating from specified procedures is high for complex interventions delivered by healthcare providers of multi-disciplinary backgrounds (Alexander & Hearld, 2012). Given this high susceptibility to context-dependent variability in implementation, it is perhaps unsurprising that demonstrable gaps remain between the current evidence-base and routine care, with complex interventions already evaluated as being effective having at most, relatively modest effects in clinical practice (Chilvers et al., 2002).

For example, good hand hygiene has been recognised as effective for preventing infections associated with healthcare (Pittet et al., 2000). Numerous interventions have been developed in an attempt to improve hand hygiene behaviour among healthcare professionals, such as increasing the number of sinks and availability of alcohol-based gels (Michie, Johnston, Abraham, et al., 2005; Pittet et al., 2000). Yet despite this, an examination of hand hygiene behaviour in an emergency department identified poor levels of hygiene, especially between consultations when procedures were not urgent or time pressured (Al-Damouk, Pudney, &

Bleetman, 2004). This provides a clear illustration of how implementation of an evidence-based practice into current clinical practice is not always optimal. More detailed examination of implementation is necessary to identify barriers and facilitators to implementation in this context. For instance, the aforementioned interventions adopt an organisational approach and target behaviour change by altering the environment, resources, and facilities. It may be necessary to also examine factors influencing motivation, such as group norms and attitudes towards hand hygiene, or knowledge of the impact on health outcomes (Michie, Johnston, Abraham, et al., 2005).

It is critical that implementation is examined if the investment in social, organisational and behavioural interventions is to be realised for maximising health. Despite the importance of examining the implementation of complex behaviour change interventions in practice, implementation research has been relatively neglected. Considerable financial investment is made annually into biomedical and clinical research, with comparably little investment into implementation and health services research (Bero et al., 1998; Eccles, Armstrong, et al., 2009). The majority of published research has been of an evaluative nature focusing on ‘producing evidence’ by assessing programme outcomes and establishing the effectiveness of the intervention. Less attention has been given to examining the quality or consistency of intervention delivery when interventions are implemented in generalised settings; both of which are needed for effective outcomes to be achieved (Barry, Domitrovich, & Lara, 2005). There is a need to move beyond the question of whether or not interventions work, towards obtaining a more sophisticated understanding as to what makes interventions work, with whom, in what circumstances, etc. To achieve this, there is a need for more research examining the process of implementation for behaviour change interventions, particularly in the naturalistic settings of clinical practice where implementation is likely to be particularly variable (Barry et al., 2005).

A systematic four-stepped approach to examining and evaluating implementation has been proposed (Durlak, 1998). First, the active ingredients of an intervention or program must be defined. Secondly, an accurate and valid system for assessing implementation of the intervention must be established. Third, this system must be applied to monitor implementation of the intervention during its execution in target settings. Lastly, implementation levels must be linked to outcomes. This approach may be applied to guide the examination of the current state of, and challenges encountered in, implementing complex behaviour change interventions.

1.4.1. Step 1: Define the ‘active ingredients’ of an intervention

A well-specified intervention is a pre-requisite for implementation and evaluation, as poorly specified interventions cannot be delivered faithfully or replicated (Michie et al., 2013). Therefore the first step before evaluating implementation is to specify precisely *what* needs to be implemented, that is, the active ingredients and components of the intervention (Durlak, 1998). A behavioural scientist designing a new behaviour change intervention, a policy maker developing new clinical guidelines, or program managers and clinicians responsible for delivering a new behaviour-change related program in clinical practice may start this process with the question: ‘how can we change a particular behaviour, such as smoking, most effectively?’ (Michie & Abraham, 2008). To answer this, such individuals may look at systematic reviews of relevant interventions to identify what has previously been done in interventions that achieved the desired behavioural outcome (i.e. effective smoking cessation behaviour change interventions). Compliance with available reporting standards and guidelines (e.g. CONSORT), should mean that the components of existing effective interventions are clearly and transparently described in the literature. It should therefore be possible to understand the context in which the original intervention was developed and evaluated, and subsequently reliably replicate some or all components of the effective

interventions in the implementers' own context with a degree of confidence as to what outcome will emerge as a result (Durlak & DuPre, 2008). However, this process may be hampered by limitations in the manner in which complex behaviour change interventions are reported.

A systematic review of the current status of evidence-based healthcare concluded that RCTs, which represent an important source of knowledge to guide evidence-based practice, are inadequately and inconsistently reported (Davidson et al., 2003). Current published intervention descriptions are often incomplete and fail to fulfil requirements outlined in reporting standards. For example, published descriptions of 41 out of 80 studies abstracted consecutively from the *Journal of Evidence-Based Medicine* were found to inadequately describe measures, intervention components, delivery procedures, and/or materials such as hand-outs or booklets (Glasziou, Meats, Heneghan, & Shepperd, 2008). Where relevant information regarding intervention content is provided, the terminology used to describe components is typically variable and vague (e.g. 'behavioural counselling,' 'problem solving') or used interchangeably (e.g. 'daily diaries/self-monitoring') (Michie, Abraham, et al., 2011). Together, this inconsistent terminology and inadequate reporting inserts uncertainty and confusion as to what the content of interventions actually is (Michie et al., 2013)

Behavioural scientists, guideline developers, and healthcare professionals encounter substantial difficulties in identifying the content of existing interventions, interpreting evidence and judging whether an effective intervention may be applicable in their context of interest (Harper, Lewin, Glenton, & Pena-Rosas, 2013). This renders it challenging to reliably use existing evidence as a basis for specifying 'best practice' in guidelines and treatment manuals. Poor specification of interventions when disseminating findings therefore

inhibits the faithful translation of evidence-based interventions into practice (Glasziou et al., 2010).

1.4.2. Step 2: Use good methods to measure implementation

Once it has been clearly specified ‘*what*’ needs to be delivered, it is necessary to ensure reliable methods are in place to monitor whether the specified active ingredients and components of the intervention are actually delivered during implementation (Durlak, 1998). This monitoring is often referred to as a process evaluation, which is typically conducted alongside intervention trials with the aim of obtaining an understanding of trial processes or underlying mechanisms in relation to context, setting, professionals, and patients (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013). Process evaluations often involve assessments of factors related to implementation, such as the fidelity and quality of intervention delivery. Treatment fidelity is defined as the ‘on going assessment, monitoring, and enhancement of the reliability and internal validity of a study’ (Borrelli et al., 2005). It consists of two general components: first, treatment differentiation- the degree to which different intervention arms in a research trial differ along important dimensions (i.e. the intervention condition is in fact different from control); secondly, treatment integrity- the extent to which a treatment is implemented as originally designed and intended (Borrelli, 2011). This involves examining *how much* of the program was administered according to intended practice as specified in relevant intervention manuals, protocols, or guidelines (i.e. adherence/quantity), in addition to the conceptually related issue of *how well* each component was delivered (i.e. quality) (Bellg et al., 2004; Durlak, 1998).

Monitoring fidelity is essential to accurately interpret intervention outcomes and increase our understanding of the relationship between interventions, their processes and outcomes. For example, if an intervention is found to be ineffective, an initial reaction may be to attribute this non-significant effect to the ‘ineffective’ intervention design. In fact, the non-significant

effect may be the result of poor implementation, in that intervention providers may have deviated from the specified procedures and failed to actually deliver the original planned intervention. Thus there is the risk of discarding a potentially effective intervention. Similarly, an effective intervention may be attributable to factors added to the intervention by providers during delivery which were not originally specified in the planned intervention. Attributing intervention outcomes to the intervention design rather than variable implementation has been referred to as a ‘Type III error’ (Barry et al., 2005). Furthermore, assessing fidelity supports the identification of intervention provider training needs and aspects of intervention delivery that require improvement.

There are numerous recommended methods for monitoring fidelity of delivery (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005; Durlak, 1998). Asking intervention providers to self-report their use of intervention components during delivery is a practical, time and resource efficient means by which to obtain information on implementation; however, such data are not always valid or reliable (Ward et al. 2013). The recommended ‘gold standard’ method for assessing fidelity of delivery is to objectively verify implementation by comparing the content of actual, delivered, practice against pre-specified criteria, such as a treatment manual. Actual practice may be verified by using audio- or video-recordings of intervention sessions or by in-session observations by independent observers. This approach is considered to yield more credible information on implementation (Borrelli, 2011; Durlak, 1998).

1.4.3. Step 3: Monitor Implementation

Monitoring fidelity of implementation is important at all stages of the implementation process, from intervention design and evaluation through to actual delivery in practice. Program drift refers to significant departures from fidelity across time, individuals and settings. It is therefore recommended that fidelity is monitored for each intervention

component and active ingredient, across multiple time points and for all intervention providers and settings if applicable (Durlak, 1998). Monitoring fidelity at multiple time points enables early detection of program drift if present, and increases confidence in the internal and external validity of resulting findings (Borrelli et al., 2005). Despite the importance of assessing fidelity, and the availability of published recommendations of fidelity assessment methods, the fidelity with which interventions are delivered is rarely assessed, and even more rarely reported (Dusenbury, Brannigan, Falco, & Hansen, 2003; Schober, Sharpe, & Schmidt, 2013). For example, of 162 studies evaluating the effectiveness preventative interventions targeting behavioural, social and academic problems, only 24% assessed fidelity of implementation (Dane & Schneider, 1998). Where fidelity has been assessed, it has been shown to be variable and often poor (Glasziou et al., 2010). A review of 38 primary prevention interventions for eating disorders in schools found that between 22% and 56% of planned intervention content was actually delivered according to protocol by intervention providers (Schober et al., 2013).

1.4.4. Step 4: Link implementation levels to outcomes

It has been demonstrated that implementation is variable and rarely 100%. The important question that arises is whether this variability has an impact on the subsequent outcomes of the intervention. However, the influence of implementation on outcomes is even more rarely examined than the level of implementation itself (Dane & Schneider, 1998; Durlak & DuPre, 2008). For example, in the same review of 162 preventative behavioural and psycho-educational interventions, only a third of the 24% of interventions assessing fidelity also examined the association between fidelity and intervention outcomes (Dane & Schneider, 1998). There is a plausible argument that when interventions are delivered as intended, consistently and well, they will produce better results than when delivery is poor or variable (Durlak & DuPre, 2008). This is supported by review evidence, demonstrating significant

associations between positive outcomes and better implementation (Dane & Schneider, 1998). In a meta-analysis of drug prevention interventions, interventions with good implementation achieved a mean effect size 0.34 greater than interventions that were poorly implemented (Tobler, 1992).

Although it has been demonstrated that better implementation typically results in better outcomes for complex behaviour change interventions, it remains unclear *how* these interventions achieve expected outcomes. Systematic reviews often highlight substantial heterogeneity in outcomes across interventions (NICE, 2007), and it is often unclear which intervention components contribute to positive outcomes (i.e. ‘the active ingredients’); to the extent that complex behaviour change interventions have been critically referred to as ‘black boxes’ (Grant et al., 2013). Identification of the active components would be facilitated if those responsible for designing and evaluating complex behaviour change interventions consistently described interventions in sufficient detail to support the precise specification of intervention content (Michie & Abraham, 2004). This would also support the ability to reliably synthesise evidence across trials in systematic reviews and to accurately interpret intervention effect sizes (Michie, Fixsen, et al., 2009).

In summary, there are numerous short-falls in fulfilling the sequential steps of the ‘ideal implementation process’ for complex behaviour change interventions. New methods are needed to address existing limitations and barriers to implementation. Improved methods for specifying and reporting complex interventions would strengthen evidence and knowledge accumulation by improving replication and implementation (Harper et al., 2013; Michie, Abraham, et al., 2011). The need for such methods has been recognised by the UK MRC guidance for developing and evaluating complex interventions (Craig et al., 2008). Alongside this, is the need for more systematic and routine assessments of fidelity and quality of delivery, particularly in the context of clinical practice.

1.5. Taxonomies of Behaviour Change Techniques: Emerging tool for monitoring and improving implementation

The British National Formulary includes key information on medications, including the basis for their selection, prescribing, dispensing, administration, components, and mechanisms of action. A similar resource is needed that provides a parsimonious list of conceptually distinct components of complex behavioural interventions, and an agreed common language for specifying and labelling such components (Michie, Fixsen, et al., 2009). In a workshop with 26 multidisciplinary researchers, such a resource was perceived as an important tool for describing interventions, achieving a mean rating of 4.4 on a scale of zero to five, with five representing greater relevance and necessity (Michie, Johnston, Francis, & Hardeman, 2005).

The recent development of a series of taxonomies of BCTs represents a first step towards developing such a resource and establishing a common language (Michie, Abraham, et al., 2011). Taxonomies are hierarchically organised, systematic, referenced nomenclatures, or technical classification systems, such as the periodic table of elements (Michie, Abraham, et al., 2011). BCTs are defined as the ‘observable, replicable and irreducible components of an intervention, that are designed to alter or redirect causal processes regulating behaviour; that is, a BCT is the proposed ‘active ingredient’’ (Abraham & Michie, 2008; Michie, Abraham, et al., 2011; Michie et al., 2013). Examples of BCTs include ‘goal setting,’ ‘self-monitoring,’ ‘biofeedback,’ and ‘problem solving’ (Michie et al., 2013). Taxonomies provide clear labels for each BCT that can be used when reporting interventions. Furthermore, each BCT is precisely defined, with specific criteria for the BCTs’ operationalization in the form of the minimum delivery specifications that would allow for the identification of a technique. For instance, ‘provide feedback’ is a BCT that is operationalized as the ‘provision of feedback to the target audience with information about the behaviour of interest’ (Michie, Abraham, et al., 2011). BCTs can be used alone or in combination, and can be delivered through

numerous formats, such as prompts, reminders, telephone calls, leaflets, signs, during intervention sessions by trained healthcare professionals and researchers, etc. (Michie, Abraham, et al., 2011). BCTs are characterised then grouped according to their behaviour change function (e.g. facilitating self-regulation).

The first BCT taxonomy developed by Abraham and Michie (2008) was a cross-behavioural domain taxonomy of 26 BCTs. This taxonomy was developed using inductive and consensus approaches, and by systematically reviewing behaviour change interventions and textbooks. Application of this taxonomy to 221 intervention descriptions extracted from published journal articles and intervention manuals, demonstrated that the taxonomy was a reliable framework for specifying the content of interventions in terms of component BCTs (Abraham & Michie, 2008). Since then, numerous taxonomies of BCTs have been developed for specific behavioural domains, including: healthy eating and physical activity (CALO-RE) (Michie, Ashford, et al., 2011), smoking cessation (Michie, Hyder, Walia, & West, 2011), alcohol consumption (Michie et al., 2012), and safer sex (Abraham, Good, Warren, Huedo-Medina, & Johnson, 2011). Most recently, an extensive, cross-behavioural domain taxonomy of 93 BCTs clustered according to 16 inductively generated groupings has been developed through a Delphi-expert consensus approach (Michie et al., 2013).

Use of taxonomies to specify intervention content holds many potential benefits for improving the development, evaluation, and implementation of complex behaviour change interventions. For example, during initial stages of intervention development, intervention designers can access a readily available, extensive list of potential BCTs to include in their interventions and use BCT definitions included in the taxonomy to produce clear guidelines in trial protocols as to how to operationalize/deliver the selected BCTs (Michie, Abraham, et al., 2011). When disseminating intervention findings, it is possible to use the taxonomy to describe intervention components in published reports using consistent terminology in order

to produce clearer, more detailed and well-defined intervention descriptions that will enable replication (Michie et al., 2013). Systematic reviewers will be able to apply a reliable method for identifying and characterising intervention content, in turn facilitating comparison across interventions and evidence synthesis to identify the specific active ingredients driving intervention outcomes. With clearer specification of intervention and control conditions, effect sizes will be more reliably interpreted (Michie, Abraham, et al., 2011). It is also possible to relate BCTs to components of theories of behaviour change to examine the mechanisms of action by which interventions achieve expected outcomes (Michie et al., 2013)

An early example the utility of this methodological approach is the work of Albarracín et al. (2005) who identified 10 BCTs that could be reliably identified from descriptions of HIV-preventative interventions, and linked these to underlying, empirically supported regulatory processes. They identified which BCTs were generally most effective (i.e. behavioural skills training) and least effective (e.g. inducing fear of HIV), and noted that some BCTs were effective in particular groups and counter-productive in others (e.g. older adults vs. young adults) (Albarracín et al., 2005). Taxonomies have since been increasingly applied in systematic reviews to identify and categorise the content of complex behaviour change interventions in terms of BCTs, which in turn has enabled identification of BCTs associated with effectiveness using methods such as meta-regression. For example, Michie et al. (2009) classified the content of behaviour change interventions targeting physical activity and healthy eating into component BCTs using a relevant taxonomy (Michie, Ashford, et al., 2011). They subsequently applied meta-regression to identify effective BCTs and theoretically derived combination of BCTs and found that the BCT ‘self-monitoring’ explained the greatest variance in outcomes (13%). Furthermore, interventions that combined ‘self-monitoring’ with additional BCTs theoretically-derived from Control Theory (Carver &

Scheier, 1982) were significantly more effective than other interventions (0.42 vs. 0.26) (Michie, Abraham, et al., 2009). BCTs associated with effectiveness have been also identified for interventions aiming to promote smoking cessation (West, Walia, Hyder, Shahab, & Michie, 2010), safe alcohol consumption (Michie et al., 2012), condom use (Abraham et al., 2011), and behaviour change in healthcare professionals (Ivers et al., 2012).

Healthcare professionals and policy makers learn about effective interventions from intervention reports, systematic reviews, or intermediaries such as clinical guidelines (Michie, Abraham, et al., 2011). Improved clarity and consistency in the specification of complex behaviour change interventions will therefore facilitate the translation and understanding of evidence amongst to healthcare professionals and policy makers (Grol & Grimshaw, 2003). This in turn should promote higher quality, evidence-based care that is implemented with higher fidelity in practice. However, this taxonomy-based method is still in early stages and continuously developing. Additional research is needed to further assess the reliability and applicability of this methodological approach.

1.6. Smoking Cessation Behavioural Support: An Implementation Case Study.

Smoking remains a leading preventable cause of excess mortality and morbidity. Cigarettes contain approximately 600 chemicals, and produce an additional 4000 chemical compounds once lit, many of which are carcinogenic or poisonous (e.g. formaldehyde, arsenic). Approximately 40% of all deaths among the middle age population are caused by smoking, and smoking is estimated to reduce a smoker's life expectancy on average by 10 years (Doll, Peto, Boreham, & Sutherland, 2005). Smoking significantly increases the risk of cardiovascular disease, chronic obstructive pulmonary disease, and several forms of cancer, including lung, bladder, and oropharyngeal (Cornfield et al., 2009; Elwood, Pearson, Skippen, & Jackson, 1984). Smoking is also linked with psychological disorders, with a smoking prevalence of approximately 60-80% in those suffering from psychosis (Banham &

Gilbody, 2010). In addition, smoking also negatively affects the health of non-smokers through secondary smoke that is passively inhaled (Oberg, Jaakkola, Woodward, Peruga, & Pruss-Ustun, 2011). Cigarette smoking is estimated to cost the National Health Service (NHS) in England between £1.4 and £1.5 billion annually (Twigg, Moon, & Walker, 2003).

Despite the well-established health risks associated with smoking, smoking prevalence remains high. In England, the most recent data on smoking rates from the Smoking Toolkit Study estimates that 18.9% of the English population were daily or non-daily smokers in July 2013 (see www.smokinginengland.info). In the 25 countries included in the European Union, the recent estimate of average population smoking prevalence was 32% (Bogdanovica, Godfrey, McNeill, & Britton, 2011). There are numerous health benefits of smoking cessation. For example, the risk of contracting lung cancer is reduced by 50%, and it has been demonstrated that the life expectancy of smokers who quit before the age of 35 exceeds that of continuing smokers by six to eight years (Doll et al., 2005; Taylor, Hasselblad, Henley, Thun, & Sloan, 2002). It is unsurprising that promoting smoking cessation therefore remains a public health priority (Niaura & Abrams, 2002). In response to the publication of the 1999 White Paper *Smoking Kills*, the UK government has demonstrated enacted multiple strategies to attempt to reduce smoking prevalence, including an advertising ban, increase in price of tobacco, and a ban on smoking in workplaces and enclosed public places (Bauld, Chesterman, Judge, Pound, & Coleman, 2003).

Approximately 70% of current adult smokers would like to quit smoking (Orleans, 2007). There are a range of interventions currently available to support smokers who are trying to quit. These interventions fall broadly into two categories: 1) pharmacological interventions, and 2) behavioural support interventions. Pharmacological interventions to aid smoking cessation include medications such as varenicline (i.e. champix), bupropion (i.e. zyban), and the numerous forms of nicotine replacement therapy (i.e. patch, inhaler, lozenge, gum,

microtab, nasal spray). These pharmacological interventions facilitate smoking cessation by targeting underlying, biological nicotine dependence and providing relief from nicotine cravings and withdrawal symptoms. There is substantial evidence illustrating the effectiveness of these different forms of pharmacological interventions, with the most effective options shown to be varenicline or a combination of two forms of nicotine replacement therapy (Brose, West, & Stapleton, 2013; Stead et al., 2012).

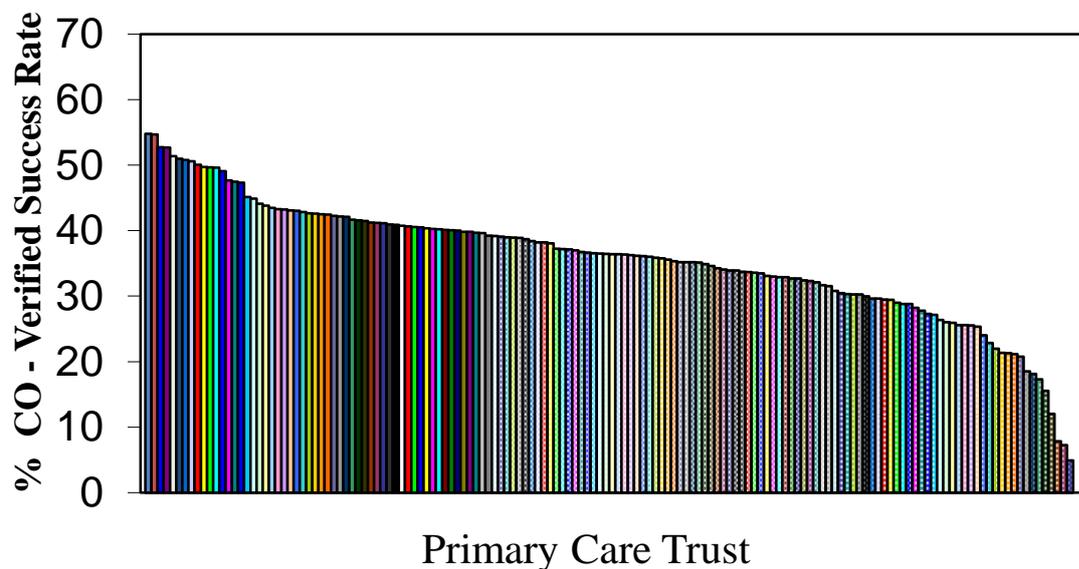
Behavioural support interventions for smoking cessation are a form of complex behaviour change intervention. Behavioural support consists of advice, discussion and targeted activities designed to minimise a smoker's motivation to smoke, maximise resolve not to smoke and to help with strategies to minimise exposures to smoking cues, cope with urges when they occur and make best use of adjunctive activities, such as smoking cessation medications (West & Stapleton, 2008). Behavioural support has been delivered through various modalities including face-to-face individual and group support sessions, internet- and telephone-based support, and has been shown to be a highly cost-effective, life-preserving intervention (Lancaster & Stead, 2005a, 2005b; Shahab & McEwen, 2009; Stead & Lancaster, 2005; Stead, Perera, & Lancaster, 2006).

Given their effectiveness and cost-effectiveness, behavioural support interventions have been implemented across the UK in clinical practice. For instance, in England, a network of 152 NHS Stop Smoking Services represent a unique national initiative to offer support to smokers who are motivated to quit (Bauld, Bell, McCullough, Richardson, & Greaves, 2010). The service provision framework followed by these services was originally based on the 'Maudsley Model' of smoking cessation treatment, an evidence-based approach to helping dependent smokers to quit (Hajek, 1989; West, McNeill, & Raw, 2000). The services offer smokers medications alongside free, weekly one-to-one or group meetings with a trained specialist practitioner, which follow a structured, withdrawal-oriented behavioural therapy

approach (Bauld et al., 2010). Smokers engaging with these services during their quit attempt are four times more likely to successfully quit than those attempting to quit unaided (Judge, Bauld, Chesterman, & Ferguson, 2005).

Despite overall success rates, outcomes across individual Stop Smoking Services are extremely heterogeneous: between April 2011 and March 2012 four-week carbon monoxide (CO) validated quit rates ranged from 2% to 58% (NHS Information Centre, 2012) (Fig. 5)

Figure 5: CO-verified success rates across NHS Stop Smoking Services 2011-2012



These data show that evidence-based behavioural support interventions are not achieving desired outcomes consistently when implemented on a large scale in clinical practice. There is limited understanding as to what factors are driving variation in outcomes across services. Observed variability in outcomes may be attributable to a range of individual-level factors such as smokers' demographic characteristics or levels of nicotine dependence (Ferguson, Bauld, Chesterman, & Judge, 2005), but also to wider service-level factors such as service configuration, funding, coordination. Another important service-level factor may be the

professional behaviour of the smoking cessation practitioners, more specifically, the content of behavioural support they deliver and how well it is delivered (Brose, McEwen, & West, 2012).

We currently have a limited understanding about how intervention content is delivered by smoking cessation practitioners. National guidelines and in-house service treatment manuals outlining the recommended content and format of smoking cessation behavioural support interventions are widely available (Croghan, 2011; West, 2000; West, Lorencatto, et al., 2010; West et al., 2000). However, there is evidence that Stop Smoking Practitioners providing support within the same service, and therefore operating in theory under the same treatment manual, have widely varying success rates (Brose, McEwen, et al., 2012). This raises the question as to whether practitioners are following the service treatment manual with fidelity when delivering support in practice. Therefore examining the behaviour of smoking cessation practitioners, that is, how they adhere to treatment manuals and what content they deliver, may increase our understanding of behavioural support practitioners currently deliver, and whether this potentially contributes in turn to variation in outcomes. Smoking cessation behavioural support delivered in clinical practice by the NHS Stop Smoking Services may thus serve as an ideal case study in which to examine the implementation of a complex behaviour change intervention in practice.

A taxonomy of smoking cessation BCTs has recently been developed that represents a potentially useful tool for examining the implementation of smoking cessation behavioural support interventions (Michie, Hyder, et al., 2011). The taxonomy was developed through the examination of key source documents and comprises 43 BCTs, each clearly labelled and precisely defined (Michie, Hyder, et al., 2011). The 43 BCTs have been characterised according to one of four behaviour change functions consistent with PRIME theory (West, 2009), which seeks to integrate the numerous influences on behaviour including ‘stimulus-

impulse associations, drive states, past experiences of pleasure and relief from discomfort, beliefs about what is good or bad, self-conscious intentions, and how these arise from associative learning, exposure to social and other cues, communication and identity'. The four functions are 1) boost motivation to quit (e.g. provide rewards contingent on effort or progress; 2) maximise self-regulatory capacity and skills (e.g. goal setting); 3) promote adjuvant activities (e.g. advise on stop smoking medication); and 4) general aspects of the interaction (e.g. building rapport).

This BCT taxonomy may potentially be used as a method for examining the various stages of the implementation process for smoking cessation behavioural support interventions. The BCT taxonomy has already been applied as a framework for specifying the components comprising behavioural support interventions. For example, the individual component BCTs comprising the content of individual- and group-based behavioural support interventions, as described in published reports and service treatment manuals, have been reliably identified and characterised using the BCT taxonomy as a coding framework (Michie, Churchill, & West, 2011; Michie, Hyder, et al., 2011; West, Evans, & Michie, 2011; West, Walia, et al., 2010). However, this BCT taxonomy methodological approach is still in its infancy and has only been evaluated in a limited number of studies. There is a need to further validate the utility and reliability of the smoking cessation BCT taxonomy as a method for specifying components of smoking cessation behavioural support interventions in other contexts. For instance, the taxonomy could also potentially be applied to reliably specify components of behavioural support interventions as actually delivered in practice, rather than as recommended in treatment manuals or as described in published intervention descriptions. This could in turn be used to assess factors related to the implementation of behavioural support interventions, such as the extent to which the components of behavioural support interventions in practice are delivered with fidelity and quality. Not only would this type of

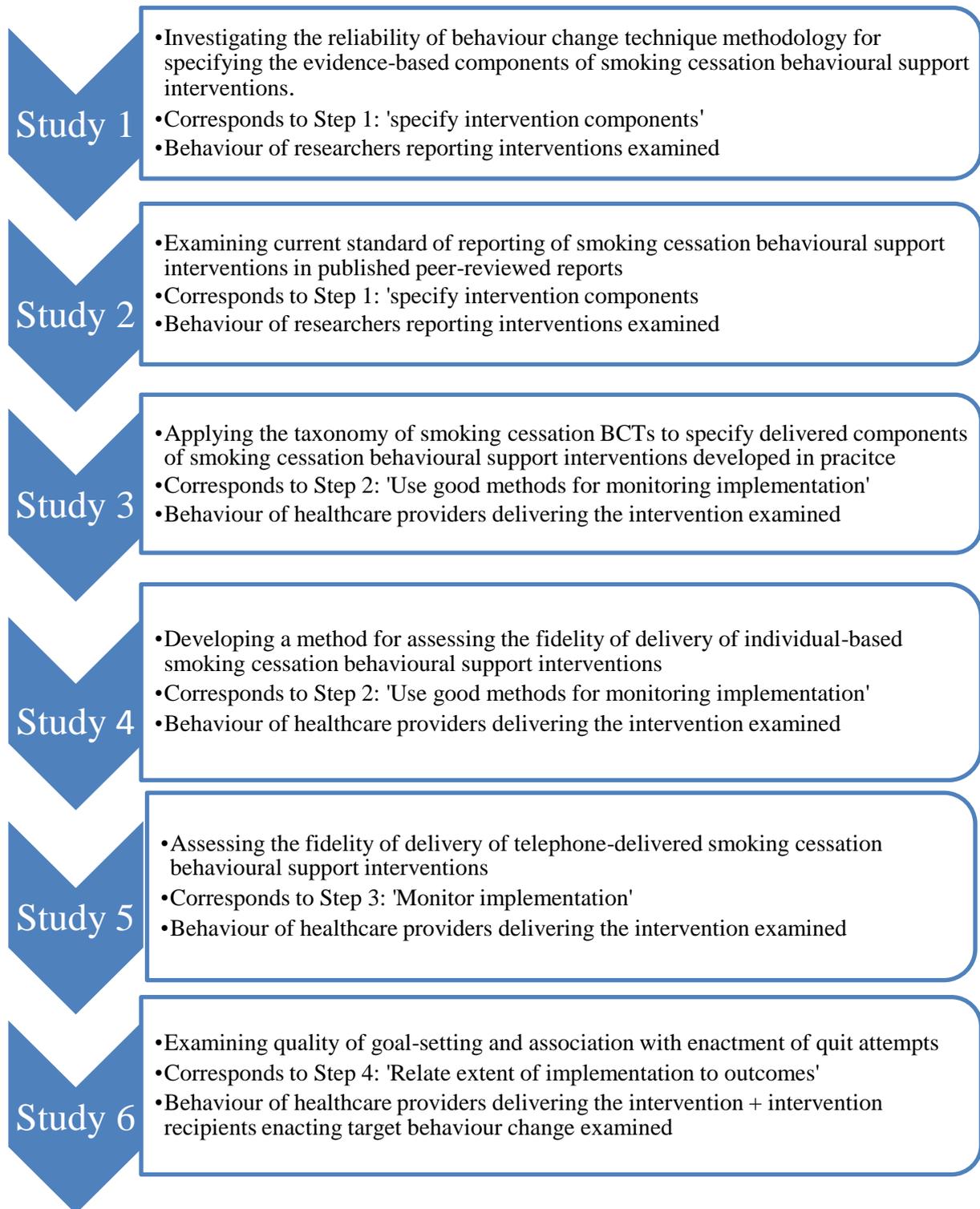
analysis provide an initial insight into current practice and the extent of implementation of evidence-based smoking cessation behavioural support interventions in practice, but it would also provide a basis for also examining the association between content of behavioural support interventions as delivered and observed variability in outcomes in clinical practice.

1.7. Aims and Objectives of the Current Thesis

The overall aim of the thesis was to examine the translation of evidence-based smoking cessation behavioural support interventions into practice, using behavioural support delivered by the NHS Stop Smoking Services as a case study, and the taxonomy of smoking cessation BCTs as a methodological framework (Michie, Hyder, et al., 2011). The thesis reports six studies that used mixed methods, and approximately corresponded to Durlak's four-staged approach to examining implementation (see Figure 6) (Durlak, 1998). The first two studies investigated the reliability of taxonomy of smoking cessation BCTs as a method for specifying the components of the behavioural support interventions. The first study used smoking cessation behavioural support interventions for pregnant smokers as an additional type of behavioural support intervention (i.e. context) to assess the reliability of the BCT taxonomy methodology for specifying evidence-based BCTs. The second study examined more generally the current standard of published reporting of the content of behavioural support interventions. The third study assessed the extent to which the taxonomy provides an accurate and valid system for specifying the component BCTs delivered in practice. The focus was on the behaviour of healthcare professionals (i.e. Stop Smoking Practitioners) and how they delivered BCTs in practice. The fourth and fifth studies built on findings from the third study and aimed to apply the taxonomy as a method for monitoring variations in fidelity of delivery of individual face-to-face and telephone-based behavioural support interventions respectively. Lastly, the sixth study developed a method for assessing the quality of delivery

of a key component of behavioural support, ‘goal setting,’ and its association with quit attempt enactment (i.e. outcomes).

Figure 6: Summary of studies included in the thesis



Therefore, the specific objectives of the studies included in this thesis were:

- 1) To examine the current specification and reporting of smoking cessation behavioural support interventions by:
 - a. Investigating the reliability of behaviour change technique methodology for specifying the evidence-based components of behavioural support for pregnant smokers (Study 1).
 - b. Evaluating the current standard with which the content of smoking cessation behavioural support interventions are reported in published intervention descriptions (Study 2).

- 2) To assess the fidelity and quality with which smoking cessation behavioural support interventions are implemented in clinical practice by:
 - a. Examining the extent to which the BCT taxonomy may be applied to reliably specify the components of behavioural support interventions as delivered in practice (study 3).
 - b. Assessing whether the taxonomy serves a reliable tool for measuring fidelity of delivery of individual- and telephone-based smoking cessation behavioural support interventions in practice (Studies 4 and 5).
 - c. Developing a method for reliably assessing the quality with which a key intervention component is delivered in practice (i.e. goal-setting) (Study 6).

- 3) To relate extent of implementation to outcomes by:
 - a. Examining the extent to which quality of goal-setting is associated with the likelihood of clients enacting a planned quit attempt in practice (Study 6).

CHAPTER 2: Investigating the reliability of behaviour change technique methodology: specifying the evidence-based components of behavioural support for pregnant smokers

2.1. Introduction

It has been demonstrated in both research and practice settings that behavioural support interventions delivered through a range of modalities are effective in aiding current smokers to successfully quit (Lancaster & Stead, 2005a; Lumley et al., 2009; Stead et al., 2013; Stead & Lancaster, 2005; Stead et al., 2006) (NHS Information Centre, 2011). However, findings from systematic reviews demonstrate substantial heterogeneity in the outcomes of behavioural support interventions (Lancaster & Stead, 2005a, 2005b; Lumley et al., 2009; Stead et al., 2013; Stead & Lancaster, 2005; Stead et al., 2006). Similarly, where these interventions have been implemented in clinical practice, such as in the NHS Stop Smoking Services, quit rates across individual services are also shown to vary substantially (NHS Information Centre, 2011). It remains unclear which specific intervention components make one behavioural support interventions intervention more effective than another. To answer this question it is necessary to identify the active ingredients comprising the content of effective interventions (Abraham & Michie, 2008). However, given the complex, multi-faceted nature of behaviour change interventions such as smoking cessation behavioural support, it is not always clear which specific components comprise the content of these interventions (Michie, Fixsen, Grimshaw, & Eccles, 2009).

A reliable coding-based method for specifying the content of smoking cessation behavioural support interventions in terms of their constituent BCTs has recently been developed (Michie, Hyder, Walia, & West, 2011). This is in the form of a taxonomy of 43 smoking cessation BCTs that are defined in detail using consistent terminology, and organised hierarchically according to four behaviour change functions: a) ‘boost motivation’ (e.g. ‘facilitate identification of reasons for wanting to stop smoking’); b) ‘maximise self-regulatory capacity and skills’ (e.g. ‘barrier identification and problem solving’); c) ‘promote adjuvant activities’ (e.g. ‘Facilitate use of social support’); and d) ‘general aspects of the interaction’ (e.g.

‘reflective listening’) (Michie, Hyder, et al., 2011). It has been demonstrated that by using this taxonomy as a coding framework, individual component BCTs can be reliably identified and categorised in published descriptions of the content of behavioural support interventions and also in treatment manuals from NHS Stop Smoking Services (Michie, Churchill, & West, 2011; West, Evans, & Michie, 2011; West, Walia, Hyder, Shahab, & Michie, 2010).

On this basis, the taxonomy has been used specify the ‘active ingredients’ of smoking cessation behavioural support interventions. Michie et al. applied the taxonomy to identify and categorise BCTs featured in published descriptions of effective individual- and group-based behavioural support interventions, and assessed which of the identified BCTs were included in multiple effective behavioural support interventions (i.e. ≥ 2); these BCTs were in turn classified as being ‘evidence-based.’ Fourteen evidence-based BCTs were identified for individual-based behavioural support, and three for group-based behavioural support (Michie, Churchill, et al., 2011). In addition, West et al. (2010) applied the taxonomy to identify BCTs present in 37 treatment manuals from the NHS Stop Smoking Services, and examined the extent to which identified BCTs were significantly associated with self-reported and CO-validated four-week quit rates in these services. Nine BCTs were significantly associated with improved CO-validated and self-reported quit rates, and an additional five BCTs were found to be significantly associated with improved self-reported quit rates only (West et al., 2010). This analysis was repeated for group-based behavioural support, identifying two further BCTs significantly associated with improved self-reported four-week quit rates (West et al., 2011).

These findings represent an important first step towards precisely specifying the active ingredients contributing to the effectiveness of smoking cessation behavioural support interventions. Treatment manuals represent an intermediary route by which evidence-based findings from research may be translated into the content of clinical practice (Wilson, 1996).

By examining BCTs in NHS Stop Smoking Service treatment manuals, these findings also provide initial insight into the extent to which BCTs are implemented in clinical practice by these services. However, this BCT taxonomy methodological approach is still in its infancy and there is a need to further validate the extent to which the BCT taxonomy consistently serves as a reliable framework for identifying and categorizing the components of complex behavioural support interventions. One way by which this may be achieved is to assess the reliability of applying the taxonomy to specify the content of different types of smoking cessation behavioural support interventions delivered in different contexts; for instance, behavioural support interventions for specialist population groups, such as pregnant smokers.

Smoking whilst pregnant is a major preventable cause of infant mortality and morbidity (Cnattingius, 2004). Some of the numerous negative health consequences associated with maternal smoking during pregnancy include: lower birth-weight, increased risk of miscarriage, and sudden death infant syndrome (Lumley et al., 2009). Despite the established health risks, it is estimated that in the UK, approximately 26% of pregnant women smoke immediately before or during pregnancy, of which 12% continue to smoke throughout and at the point of delivery (NHS Information Centre, 2011). Only recently has good evidence emerged for the efficacy of nicotine replacement therapy in pregnancy (Brose, McEwen, & West, 2013), and other stop-smoking medications are contraindicated during pregnancy (NICE, 2011). Conversely, there is evidence from RCTs that behavioural support interventions for pregnant smokers are effective and cost-effective (Lumley et al., 2009). Furthermore, many NHS Stop Smoking Services offer free specialist behavioural support tailored to the unique needs of specialist population groups, including pregnant smokers. Of the 21, 839 pregnant women setting a quit date with a NHS Stop Smoking Service in 2010/2011, 27% were abstinent at four-week follow up, confirmed by CO-verification (NHS Information Centre 2011). However, as is the case with behavioural support interventions

more generally, there is substantial heterogeneity in the outcomes of pregnancy behavioural support interventions across research trials and services in clinical practice (Lumley et al., 2009) (NHS Information Centre 2011). It is similarly unclear which BCTs contribute to effective outcomes in these specialist interventions, and whether these differ from behavioural support interventions not targeted at a specific population group (i.e. ‘generic’). There is also limited understanding regarding the extent to which BCTs forming behavioural support interventions in effective trials are subsequently implemented in practice by the NHS Stop Smoking Services.

This study had two principal aims: (1) to further assess the extent to which a novel BCT taxonomy methodology provides a reliable framework for systematically specifying the content of smoking cessation behavioural support interventions by applying it to the context of smoking cessation behavioural support interventions in pregnancy; (2) to use this analysis in turn to examine which component BCTs comprise *effective* smoking cessation behavioural support interventions for pregnant smokers. A secondary aim of this study was to assess the extent to which BCTs identified as evidence-based for smoking cessation in pregnancy feature in specialist NHS Stop Smoking Service treatment manuals, in order to initially examine implementation of evidence-based findings into clinical practice for this type of behavioural support.

2.1.1. Aims and Objectives

In summary, the specific objectives of this study are:

1. To establish the extent to which the taxonomy of smoking cessation BCTs continues to serve as a reliable framework for specifying the components of smoking cessation behavioural support interventions in the context of a new population- pregnant smokers.

2. To assess which component BCTs feature in the content of multiple effective behavioural support interventions for smoking cessation in pregnancy, and are therefore classifiable as evidence-based.
3. To examine the extent to which identified evidence-based BCTs for smoking cessation in pregnancy feature in treatment manuals from specialist NHS Stop Smoking Services for pregnant smokers.

2.2. Methods

This study followed the methods of Michie, Churchill, and West (2011) and was conducted in two stages.

2.2.1. Stage 1: Assessing the reliability of the BCT taxonomy for specifying evidence-based BCTs for smoking cessation behavioural support in pregnancy

Sample and materials

Component BCTs included in effective behavioural support interventions were specified by applying a published taxonomy of 43 smoking cessation BCTs as a coding framework (Michie, Hyder, et al., 2011). Effective intervention packages were identified from the Cochrane Review: '*Interventions for promoting smoking cessation in pregnancy*' (Lumley et al., 2009). The same criteria applied by Michie et al. (2011) were utilised to classify interventions as effective or ineffective: an intervention was classified as effective if it increased the probability of cessation by at least 50% (i.e. $OR \geq 1.50$), and the differences between the intervention and control group were statistically significant (i.e. $p < .05$) (Michie, Churchill, et al., 2011). Given the recognised inadequate reporting of intervention content in published intervention descriptions (Glasziou et al., 2008), the lead authors of the interventions identified as effective, and therefore included in the current analysis, were

contacted on up to two occasions with a request for their trial protocol or any additional available materials further detailing the intervention's content; where no protocol was available or no response received, the intervention description in the corresponding published trial report was utilised for analysis.

Procedure

Coding to specify intervention content into component BCTs was conducted by a researcher with extensive experience in using the taxonomy as a coding framework. The description of the content of each effective intervention was coded for the inclusion of each of the 43 BCTs in the taxonomy, by assigning BCT labels where appropriate to sections of the trial report or protocol that described the intervention treatment condition. Data on the BCTs identified and the frequency of BCTs used across trials were extracted throughout. A BCT was classified as 'evidence-based' if it featured in at least two of the effective interventions included in the review (criteria from Michie, Churchill, & West 2011). The subset of BCTs identified as evidence-based for smoking cessation in pregnancy was then compared with the subset of BCTs previously identified as evidence-based for 'generic' individual behavioural support (n=14 BCTs; Michie et al. 2011), and to the set of BCTs associated with improved four-week quit outcomes in the NHS SSSs (n=14; West et al. 2010).

2.2.2. Stage 2: Examining prevalence of use of evidence-based BCTs by the NHS SSSs

Sample and materials

Treatment manuals from NHS SSSs were obtained in order to examine the extent to which they featured BCTs identified as evidence-based in Stage 1. Service Managers from all English NHS primary care trusts (PCTs; n=152) were contacted on up to three occasions with a request for any available service treatment manuals or guidance documents outlining recommendations and specifications for the format and content of sessions to be delivered as

part of specialist behavioural support to pregnant smokers. Two independent researchers assessed the documents received to determine whether they constituted a treatment manual. A treatment manual was presently defined as: ‘a formal written plan specifying procedures to be followed in providing a specific treatment or support for smoking cessation to pregnant smokers.’

Procedure

Treatment manuals were coded into component BCTs using the taxonomy, following the same coding procedures as for Stage 1. The proportion of service treatment manuals that contained all identified evidence-based BCTs for pregnancy-specific support, and that which contained at least 50% of the identified BCTs, was noted.

2.2.3. Inter-Rater Reliability Analyses

For published trial descriptions, trial protocols and service treatment manuals, a second researcher with equivalent experience in coding using the taxonomy, independently coded a subset of materials (33%). Inter-rater reliability was assessed to check the extent to which the independent coders agreed that the same BCT could be identified from intervention descriptions. Reliability was assessed using percentage-agreement. Where one coder failed to identify a BCT, or a different BCT was identified, disagreement was registered. Discrepancies were resolved through discussion or consultation with a behaviour change expert.

2.3. Results

2.3.1. Stage 1: Assessing the reliability of the BCT taxonomy for specifying evidence-based BCTs for smoking cessation behavioural support in pregnancy

Identification of Effective interventions

The Cochrane review of behavioural interventions for promoting smoking cessation in pregnancy included 56 RCTs. Of these, seven interventions were classified as effective according to our criteria, all of which were RCTs of one-to-one behavioural support (Donatelle, Prows, Champeau, & Hudson, 2000; Heil et al., 2008; Higgins et al., 2004; Hjalmarson, Hahn, & Svanberg, 1991; Lawrence, Aveyard, Evans, & Cheng, 2003; Polanska, Hanke, Sobala, & Lowe, 2004; Walsh, Redman, Brinsmead, Byrne, & Melmeth, 1997). Three studies were conducted in the United States, three in Europe (UK, Poland, Sweden) and one in Australia. A trial protocol and additional intervention content was received for only one trial (Walsh et al., 1997). For the remaining six trials, published intervention descriptions were utilised for analysis.

Inter-rater coding reliability

Inter-rater coding reliability of intervention descriptions in trial reports/protocols was high (93% agreement). All discrepancies were resolved through discussion.

Identification of evidence-based BCTs

Thirty-seven of the original 43 (86%) BCTs included in the taxonomy were identified at least once across effective trials of behavioural support for pregnant smokers (Table 1). No new BCTs not already included in the taxonomy were identified during coding. The number of BCTs identified per effective behavioural support intervention ranged from six to thirty-four, with an average of eight BCTs per intervention (SD=9.9). Eleven BCTs (29.7%) were

identified in at least two interventions, therefore meeting our effectiveness criteria (Table 2). Of these, three (27.2%) served the behaviour change function ‘boost motivation,’ four (36.4%) served the function ‘maximising self-regulatory capacity and skills,’ one (9.1%) served ‘promoting adjuvant activities,’ and three (27.2%) pertained to ‘general aspects of the interaction’ (Table 1).

Table 1. The frequency of BCTs identified in effective behavioural support interventions, grouped according to behaviour change function.

BCT Code	BCT Label	BCT definition	Number of effective interventions (max n=7)
<i>Specific focus on the target behaviour (B) and maximising motivation (M)</i>			
BM1	Provide information on consequences of smoking and smoking cessation	Give, or make more salient, information about the harm caused by smoking and the benefits of stopping; distinguish between the harms from smoking and nicotine; debunk myths about low tar and own-roll cigarettes and cutting down	7
BM2	Boost motivation and self-efficacy	Give encouragement and bolster confidence in ability to stop	1
BM3	Provide feedback on current behaviour	Give feedback arising from assessment of current self-reported or objectively monitored behaviour (e.g. expired-air CO) and/or progress towards becoming a permanent non-smoker	1
BM4	Provide rewards contingent on successfully stopping smoking	Give praise or other rewards if the person has not smoked	4
BM5	Provide normative information about others' behaviour and experiences	Give information about how the smoker's experience compares with other people's	1
BM6	Prompt commitment from the client there and then	Encourage the smoker to affirm or reaffirm a strong commitment to start, continue or restart the quit attempt	1
BM7	Provide rewards contingent on effort or progress	Give praise or other rewards for the effort the smoker is making and if the smoker has engaged in activities such as correct use of medication that aid cessation	1
BM8	Strengthen ex-smoker identity	Explain the importance of regarding smoking as something that is 'not an option', including the 'not a puff' (NAP) rule, encourage the smoker to re-evaluate the attraction to smoking, and construct a new identity as someone who 'used to smoke'	1

BM9	Identify reasons for wanting and not wanting to stop smoking	Help the smoker to arrive at a clear understanding of his or her feelings about stopping smoking, why it is important to stop and any conflicting motivations	1
BM10	Explain the importance of abrupt cessation	Explain why it is better to stop abruptly rather than cut down gradually if at all possible	1
BM11	Measure CO	Measure expired-air carbon monoxide concentration	6

Maximising self-regulatory capacity and skill (BS)

BS1	Facilitate barrier identification and problem solving	Help the smoker to identify general barriers (e.g. susceptibility to stress) that might make it harder to stay off cigarettes and develop general ways of addressing these	2
BS2	Facilitate relapse prevention and coping	Help the smoker understand how lapses occur and how they lead to relapse and to develop specific strategies for preventing lapses or avoiding lapses turning into relapse	3
BS3	Facilitate action planning/develop treatment plan	Work with smoker to generate a clear quit plan including preparations for the quit attempt (e.g. obtaining medication)	5
BS4	Facilitate goal setting	Help the smoker to set a quit date and goals that support the aim of remaining abstinent	6
BS5	Prompt review of goals	Review how far the smoker has achieved the main goal of abstinence and any other goals that are supportive of it (e.g. putting in place plans to avoid triggers)	1
BS6	Prompt self-recording	Help the smoker to establish a routine of recording potentially useful information (e.g. situations or times when urges are strong and less strong)	0
BS7	Advise on changing routine	Advise on ways of changing daily or weekly routines to minimise exposure to smoking cues	1
BS8	Advise on environmental restructuring	Advise on ways of changing the physical environment to minimise exposure to smoking cues (e.g. removing ashtrays from the house)	1
BS9	Set graded tasks	Set small achievable goals where appropriate (e.g. take one day at a time)	1
BS10	Advise on conserving mental resources	Advise on ways of minimising stress and other demands on mental resources (activities that require mental effort)	1

BS11	Advise on avoiding social cues for smoking	Give specific advice on how to avoid being exposed to social cues for smoking (e.g. explaining to friends that you have stopped)	1
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Promoting adjuvant activities (A)

A1	Advise on stop-smoking medication	Explain the benefits of medication, safety, potential side effects, contra-indications, how to use them most effectively, and how to get them; advise on the most appropriate medication for the smoker and promote effective use	1
A2	Advise on/facilitate use of social support	Advise on or facilitate development of social support from friends, relatives, colleagues or 'buddies'	2
A3	Adopt appropriate local procedures to enable clients to obtain free medication	Enact the necessary procedures to ensure that the smoker gets his/her medication easily and without charge where appropriate	0
A4	Ask about experiences of stop smoking medication that the smoker is using	Assess usage, side effects and benefits experienced of medication(s) that the smoker is currently using	0
A5	Give options for additional and later support	Give information about options for additional support where these are available (e.g. websites, self-help groups, telephone helpline)	1

General aspects of the role/interaction (RC)

RD1	Tailor interactions appropriately	Use relevant information from the client to tailor the behavioural support provided	0
RD2	Emphasise choice	Emphasise client choice within the bounds of evidence based practice	1
RI1	Assess current and past smoking behaviour	Assess amount smoked, age when started, pattern of smoking behaviour	7
RI2	Assess current readiness and ability to quit	Assess current level of motivation to stop and confidence in success	5
RI3	Assess past history of quit attempts	Assess number and duration of past quit attempts and experiences related to these, including factors that led back to smoking	1

RI4	Assess withdrawal symptoms	Assess the presence and severity of nicotine withdrawal signs and symptoms	0
RC1	Build general rapport	Establish a positive, friendly and professional relationship with the smoker and foster a sense that the smoker's experiences are understood	1
RC2	Elicit and answer questions	Prompt questions from the smoker and answer clearly and accurately	1
RC3	Explain the purpose of CO monitoring	Explain to the smoker the reasons for measuring CO at different time points, e.g. before and after the quit date	0
RC4	Explain expectations regarding treatment programme	Explain to the smoker the treatment programme, what it involves, the active ingredients and what it requires of the smoker	1
RC5	Offer/direct towards appropriate written materials	Distinguish what are, and are not, appropriate written materials and offer/direct clients to these in ways that promote their effective use	7
RC6	Provide information on withdrawal symptoms	Describe to smokers what are, and are not, nicotine withdrawal symptoms, how common they are, how long they typically last, what causes them and what can be done to alleviate them	1
RC7	Use reflective listening	Adopt a style of interaction that involves listening carefully to the smoker and where appropriate reflecting back to the smoker key elements of what s/he is saying	1
RC8	Elicit client views	Prompt the client to give views on smoking, smoking cessation and any aspects of the behavioural support programme	1
RC9	Summarise information / confirm client decisions	Provide a summary of information exchanged and establish a clear confirmation of decisions made and commitments entered into	1
RC10	Provide reassurance	Give general reassurance to the smoker that his/her experiences are normal and time limited, and provide positive expectations of success based on experience with other smokers in the same situation	1

Note: BCT= behaviour change technique; CO= expired-air carbon monoxide.

Of the eleven identified evidence-based BCTs for behavioural support in pregnancy, nine (81.1%) were also featured in the set of evidence-based BCTs for generic one-to-one behavioural support (Michie, Churchill, et al., 2011). The two BCTs in the sub-set of evidence-based BCTs for smoking cessation in pregnancy that were not included in the set of generic evidence-based BCTs were: ‘advise on/facilitate use of social support’ and ‘provide rewards contingent on successfully stopping smoking.’ Of the eleven evidence-based BCTs presently identified, four (28.6%) were also included in the set of BCTs associated with improved four-week quit rates in the NHS Stop Smoking Services (West et al., 2010). These were: ‘provide rewards contingent on successfully stopping smoking,’ ‘measure CO,’ ‘Facilitate use of social support’ and ‘facilitate relapse prevention and coping’ (Table 2).

Table 2. Evidence-based BCTs (identified in ≥ 2 effective RCTs) for specialist pregnancy behavioural support compared to BCTs previously identified as evidence-based for generic individual behavioural support^a and as associated with improved 4-week quit outcomes.^b

BCT	Evidence-based for Specialist pregnancy behavioural support	Evidence-based for generic individual behavioural support^a	Associated with four week quit outcomes^b
BM4 Provide rewards contingent on successfully stopping smoking	✓	✓	✓
BM11 Measure CO	✓	✓	✓
BS2 Facilitate relapse prevention and coping	✓	✓	✓
BM1 Provide information on the consequences of smoking and smoking cessation	✓	✓	X
BS1 Facilitate barrier identification and problem solving	✓	✓	X
BS3 Facilitate action planning/ identify relapse triggers	✓	✓	X
BS4 Facilitate goal setting	✓	✓	X
RI1 Assess current and past smoking behaviour	✓	✓	X
RI2 Assess current readiness and ability to quit	✓	✓	X
RC5 Offer/Direct towards appropriate written materials	✓	✓	X
A2 Advise on/facilitate use of social support	✓	X	✓
A1 Advise on stop smoking medication	X	✓	✓
A5 Give options for additional and later support	X	✓	✓
RC6 Provide information on withdrawal symptoms	X	✓	X

RI3 Asses past history of quit attempts	X	✓	X
BM6 Prompt commitment from the client there and then	X	X	X
RC8 Elicit Client views	X	X	✓
BS7 Advise on changing routine	X	X	✓
A3 Ask about experiences of stop smoking medications that the Smoker is using	X	X	✓
BS10 Advise on conserving mental resources	X	X	✓
RC9 Summarise information/ confirm Client decisions	X	X	✓
RC10 Provide reassurance	X	X	✓
BM2 Boost motivation and self-efficacy	X	X	✓

^a From Michie, Churchill & West 2010; ^b From West, Walia, Michie et al. 2011

2.3.2. Stage 2: Examining prevalence of use of evidence-based BCTs by the NHS Stop Smoking Services

Response Rate and Obtaining of Treatment Manuals

Of the 152 NHS Stop Smoking Service Managers contacted, 128 (84%) responded. Of these, 113 (88%) reported having a service dedicated to providing behavioural support to pregnant smokers. Of these, only 32 (25%) reported having treatment manuals. Documents were received from 23 (72%) of services possessing manuals, of which only 13 (57%) were classified as manuals according to the present study definition and contained sufficient detail and information to enable identification of BCTs.

Inter-rater coding reliability

Inter-rater coding reliability of intervention descriptions in service treatment manuals was high (88% agreement). All discrepancies were resolved through discussion.

Identification of evidence-based BCTs in service treatment manuals

Manuals contained a range of 2-11 BCTs per manual, with an average of seven BCTs per manual ($SD=2.79$) (Table 3). Two manuals contained all eleven evidence-based BCTs (15.4%). Seven manuals (53.8%) contained more than half (i.e. at least six) of the identified evidence-based BCTs (Table 3).

Table 3. Prevalence of identified evidence-based BCTs in NHS Stop Smoking Service (SSS) treatment manuals (n=13) for smoking cessation behavioural support in pregnancy

BCT	SSS 1	SSS 2	SSS 3	SSS 4	SSS 5	SSS 6	SSS 7	SSS 8	SSS 9	SSS 10	SSS 11	SSS 12	SSS 13
BM11 Measure CO	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
RC5 Offer/ Direct towards appropriate written materials		✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓
BM1 Provide information on the consequences of smoking and smoking cessation	✓	✓		✓		✓	✓	✓	✓	✓		✓	✓
RI2 Assess current readiness and ability to quit	✓			✓	✓	✓		✓	✓	✓	✓	✓	
BM4 Provide rewards contingent on successfully stopping smoking	✓	✓		✓				✓	✓	✓	✓	✓	
BS3 Facilitate action planning		✓				✓	✓	✓	✓	✓	✓	✓	
BS4 Facilitate goal setting		✓			✓	✓		✓	✓	✓	✓	✓	
A2 Advise	✓			✓		✓	✓	✓		✓		✓	✓

on/facilitate use of
social support

BS2	Facilitate relapse prevention and coping	✓		✓		✓	✓	✓		✓	✓	✓		
RI1	Assess current and past smoking behaviour	✓		✓		✓				✓		✓	✓	
BS1	Facilitate barrier identification and problem solving					✓		✓		✓	✓	✓		
Total		6	7	2	8	4	10	6	10	6	11	8	11	5

2.4. Discussion

It was possible to reliably apply a novel, taxonomy-based, methodological approach to formally and systematically classify the content of behavioural support interventions for pregnant smokers according to their component BCTs. On the basis of this, it was possible to link individual BCTs with outcomes by reliably identifying which BCTs consistently featured in the content of interventions with demonstrated effectiveness in this population group. Eleven evidence-based BCTs for smoking cessation behavioural support in pregnancy were identified from published descriptions of the content of effective behavioural support interventions for pregnant smokers. This sub-set of BCTs includes at least one BCT addressing each of the four behaviour change functions outlined by the taxonomy. Behaviour change functions reflect the mechanisms by which BCTs work to support smoking cessation, for example, by boosting motivation or facilitating self-regulation. The four behaviour change functions embedded in the structure of the taxonomy are consistent with a wider theory of motivation developed in relation to smoking cessation, PRIME theory (West, 2009). By systematically identifying and labelling component BCTs in effective interventions, it is possible to examine and clearly describe behavioural support interventions by their key active ingredients and corresponding mechanisms of action, and to link these to overarching theoretical frameworks.

The set of evidence-based BCTs for behavioural support in pregnancy is largely consistent with the sets of BCTs previously identified as comprising effective individual-based behavioural support interventions more generally (Michie, Churchill, et al., 2011), and as being associated significantly with improved quit rates in clinical practice (West et al., 2010). Only two BCTs presently identified as evidence-based for smoking cessation in pregnancy were not also identified as evidence-based for ‘generic’ behavioural support interventions: ‘provide rewards

contingent on successfully stopping smoking’ and ‘facilitate use of social support.’ This finding is to an extent unsurprising. A review of the use of incentives in smoking cessation interventions with pregnant smokers found that rewards and incentives have been incorporated into worksite and community-based interventions with pregnant smokers to achieve successful quit outcomes, particularly with pregnant women of lower socioeconomic status (Donatelle et al., 2004). Similarly, providing positive social support, such as by giving compliments and expressing willingness to help with daily activities, has been found to be associated with improved quit outcomes in pregnancy (McBride et al., 1998). There is also evidence suggesting that pregnant women are more likely to notice their partner’s social support during a quit attempt than non-pregnant women (Haug, Fugelli, Aaro, & Foss, 1994). The emergence of BCTs uniquely evidence-based for pregnancy-specific behavioural support interventions helps establish the active ingredients of interventions for this group and highlights the potential need to tailor support provided to the unique needs of pregnant women. These findings provide some evidence for the inclusion of these BCTs in the design of optimised smoking cessation interventions and services in clinical practice for pregnant smokers.

In addition to specifying the active component BCTs in effective behavioural support interventions, the application of the taxonomy to reliably specify BCTs comprising NHS service treatment manuals provides an initial insight into particular stages of the implementation process for smoking cessation behavioural support interventions. The first stages of the implementation process involve establishing and disseminating evidence (see Figure 4, Chapter 1). Subsequently this evidence may be translated into practice directly or through intermediary routes such as treatment manuals, which outline evidence-based recommendations for healthcare professionals delivering an intervention in practice (Figure 4). Despite a large proportion of NHS Stop

Smoking Services stating that they provide a specialist cessation service for pregnant smokers, it was found that only a very small proportion of services had dedicated treatment manuals for this. This in turn increases the scope for variability in the content of support delivered in practice by specialist practitioners within the services that currently operate in the absence of a treatment manual. In the services from which manuals were obtained, current recommendations for the content of support to be delivered do not frequently feature the BCTs identified as evidence-based. Most of the existing treatment manuals examined contained at least half of the eleven evidence-based BCTs identified, but only two manuals contained all eleven. In order for evidence regarding what makes an effective intervention to influence practice, healthcare professionals must first be informed of these findings. It would seem appropriate to further align practice in terms of the content of treatment manuals with the identified evidence base.

This study had several limitations. There are numerous factors that influence outcomes of behavioural support interventions other than their content, such as general communication and therapeutic skills, methods of delivery and setting (Davidson et al., 2003); however, these are rarely mentioned in published trial reports (Glasziou et al., 2010). Precisely specifying the content of interventions is inherently problematic due to such inadequacies in intervention reporting. Despite efforts to access further information on intervention content, the presently available intervention descriptions examined were vague and employed variable terminology. Consequently, it is possible that the descriptions examined provided an incomplete picture as to what the original interventions actually comprised, thus potentially reducing the validity of the current findings. This issue has been recognised in previous attempts to apply taxonomies to characterise intervention content (Hardeman, Griffin, Johnston, Kinmonth, & Wareham, 2000; Martin, Chater, & Lorencatto, 2013).

A second issue relates to the ability to isolate and assess the effect of individual BCTs on outcomes (Martin et al., 2013). Ideally the evidence-base of BCTs would be established by examining the associations between individual techniques and outcomes in effective and ineffective interventions. However, in the present study both the descriptions of intervention content and the number of trials available were too limited to support analytic methods such as meta-regression, which would partial out the influence of additional influencing factors and analyse effectiveness by individual BCT. Meta-regression has previously been combined with taxonomy specification methodology to identify effective BCTs for interventions in other behavioural domains, such as physical activity and healthy eating (Michie, Abraham, et al., 2009; Olander et al., 2013). Furthermore, our findings were limited to examining which *individual* BCTs comprised effective interventions. We did not examine the inclusion of different *combinations* of BCTs in effective interventions. For instance, Dumbrowski et al examined the effect of combining theory-congruent clusters of BCTs on outcomes of interventions targeting obese adults. They found that interventions that included combinations of BCTs congruent with Control Theory (Carver & Scheier, 1982) were associated with increased effectiveness (Dumbrowski et al., 2012). In the present study it was therefore not possible to infer whether BCTs featured in effective interventions as a result of being ‘combined’ with other BCTs, or whether, if when combined differently they would no longer be linked to effectiveness. It is worth noting that BCTs not presently identified as evidence-based may have been linked to effective intervention outcomes if combined alternatively with other BCTs or in different populations and settings (Martin et al., 2013).

Therefore, although a set of 11 component BCTs were identified as evidence-based for behavioural support interventions in pregnancy, other BCTs from the full taxonomy may also be

relevant but did not feature in sufficient studies to enable identification. This is likely given that the present set of evidence-based BCTs were identified from only seven trials; had more effective trials been identified or examined then potentially additional evidence-based BCTs or combination of BCTs may have been identified as relevant. Similarly, five BCTs previously established as evidence based for generic individual behavioural support were not presently identified as evidence based for specialist pregnancy support (Michie, Churchill, et al., 2011). These were: ‘advise on stop smoking medication,’ ‘give options for additional/later support,’ ‘provide information on withdrawal symptoms,’ ‘assess past history of quit attempts,’ and ‘prompt commitment from the client.’ Yet, all of the latter techniques are likely to be of some relevance to smoking cessation in pregnancy. For example, there are numerous contraindications and restrictions for the use of smoking cessation medications in pregnancy (NICE, 2011). Therefore, delivering the BCT ‘advise on stop smoking medications’ is likely to be relevant also to stop smoking support in pregnancy. Also, while some BCTs may be important in their own right for effectively helping smokers to quit, others BCTs such as ‘building rapport’ may play more of an adjunctive role, supporting the delivery of other BCTs. Practitioners delivering interventions may thus consider applying other component BCTs from the taxonomy in addition to those identified as evidence-based in this study.

A further limitation is that treatment manuals were examined rather than measures of actual practice when assessing the potential implementation of evidence-based BCTs in practice by the NHS Stop Smoking Services. Translation of intended or recommended practice, as specified in treatment manuals, into actual practice is rarely uniform and often lacks intervention fidelity (Borrelli, 2011). Further research is needed to investigate whether evidence-based BCTs are actually delivered in practice. This could potentially be achieved by applying the taxonomy to

code audio-recorded or video-recorded behavioural support sessions into component BCTs. However, the extent to which the taxonomy would be a reliable framework when applied in this manner is currently unknown.

In conclusion, given the current state of the evidence and reporting of interventions, the present methods represent the best available initial step towards specifying the content of effective behavioural support interventions. This adds to the existing evidence-base demonstrating the utility of the taxonomy as methodological approach for systematically and reliably specifying the content of complex interventions into BCTs using consistent terminology and labels. This approach in turn illustrates how the specification of intervention content can be clarified. These findings contribute to the knowledge base as to which interventions are most likely to be effective, by increasing our understanding as to *what* and *how* these complex behaviour change interventions for smoking cessation work. Furthermore, this study highlights current difficulties in specifying the components of interventions, and provides an initial snapshot of potential gaps between evidence-based findings and current clinical practice.

2.5. Citation for the published peer-reviewed journal article for this study

Lorencatto, F., West, R., & Michie, S. (2012). Specifying evidence-based behavior change techniques to aid smoking cessation in pregnancy. *Nicotine Tob Res*, *14*(9), 1019-1026.

doi: 10.1093/ntr/ntr324

For published-peer reviewed article see Appendix 11.

**CHAPTER 3: How well is intervention content described in published reports
of smoking cessation interventions?**

3.1. Introduction

In order for research evidence to influence practice it must first be made available and disseminated as widely as possible. One of the primary means by which this is achieved is through the publication of research findings in peer-reviewed academic journals (Grimshaw & Eccles, 2004). Researchers designing new interventions, policy makers, guideline developers, and healthcare professionals, look to the literature in order to establish what is and is not effective in achieving desired behavioural outcomes (Davidson et al., 2003). Therefore, for research findings to be accessible and useful, it is necessary to effectively, clearly and consistently communicate information about evidence-based health behaviour change interventions (Des Jarlais, Lyles, & Crepaz, 2004; Harper, Lewin, Glenton, & Pena-Rosas, 2013). Detailed reporting of intervention components is a pre-requisite for the accurate replication and faithful implementation of interventions in new settings or populations. Furthermore, transparent reporting is integral to building on existing research findings to generate scientific knowledge regarding behaviour change (West, 2008). For example, it is necessary to have data for the use of meta-regression techniques to accurately identify sources of heterogeneity in systematic reviews and to develop improved interventions for further evaluation (Michie, Rothman, & Sheeran, 2007).

Behaviour change interventions are complex, comprising multiple components (Craig et al., 2008). There are two main categories of intervention components. First, components relating to the mode and delivery of interventions, such as provider, format, setting, intensity, duration, fidelity, etc. Secondly, components relating to the content of interventions- the constituent intervention behaviour change techniques (BCTs) (Davidson et al., 2003; Dombrowski et al., 2012). Guidelines to facilitate and promote the transparent reporting of intervention components

have recently been published. These include the CONSORT statement for randomized controlled trials (RCTs) (Moher, Schulz, & Altman, 2001), and subsequent extensions of CONSORT to other designs, such as RCTs of non-pharmacological interventions (Boutron, Moher, Altman, Schulz, & Ravaud, 2008). All of these guidelines call for the reporting of the ‘precise details of the interventions as actually administered,’ which should be described in sufficient detail to allow accurate replication (Davidson et al., 2003). These requirements are echoed in the American Psychological Association’s Journal Article Reporting Standard (JARS) (APA, 2008).

Despite the availability of these guidelines, current reporting of complex interventions is generally inadequate in terms of detail (Michie, Fixsen, Grimshaw, & Eccles, 2009). Published descriptions of interventions often focus on results of evaluations and on describing components of intervention delivery rather than content (Glasziou et al., 2010; Michie & Abraham, 2004). Reviews of approximately 1,000 published studies of behaviour change interventions found that only 5% to 30% of studies examined were described in detail (Dane & Schneider, 1998; Gresham, Gansle, & Noell, 1993; Moncher & Prinz, 1991; Odom et al., 2003). A systematic review of interventions for back pain found that only 13% of papers reported the interventions in sufficient detail for them to be deemed reproducible (Glenton, Underland, Kho, Pennick, & Oxman, 2006). Of 480 RCTs identified in leading medical journals, approximately just 57% were found to adhere to the CONSORT standard (Folkes, Urquhart, & Grunfeld, 2008). Moreover, obtaining access to further information on the original, intervention components is rarely straightforward, with few published intervention evaluations referring to formal documentation that provides additional detail on the content and delivery of an intervention, such as a trial protocol (Michie et al., 2007).

An additional issue is the lack of consensus on the terminology used to describe intervention components. Labels for intervention components are often vague, such as ‘behavioural counselling,’ or ‘problem solving;’ these can all potentially be interpreted differently according to the individuals responsible for evaluating or delivering an intervention (Michie et al., 2007). Furthermore, the same intervention component can be described using different labels (i.e. ‘daily diaries’ and ‘self-monitoring’), and conversely, different components can be described using the same label (i.e. ‘behavioural counselling’ can involve both ‘educating’ patients and ‘providing feedback’) (Michie, Abraham, et al., 2011). Together, incomplete reporting and inconsistent terminology produce confusion that results in a limited understanding about the details of an intervention and of the functional relationship between intervention components and outcomes (i.e. the ‘active ingredients’) (Michie, Fixsen, et al., 2009).

In contrast, pharmacological interventions have to be precisely specified, with the specific content (i.e. chemical composition), dose, and frequency of administration of medications clearly and consistently defined in resources such as the *British National Formulary*. If pharmacological interventions were to be specified inadequately, using the same vague terminology as is often the case for behavioural interventions, the equivalent description would be ‘small white pill.’ This difference in the level of specification between pharmacological and behavioural interventions could account for the finding that a panel of 26 multidisciplinary researchers reported greater confidence in replicating a pharmacological intervention than a behaviour change intervention (Michie, Johnston, Francis, & Hardeman, 2005).

Such a contrast in the degree of specification and confidence in replicating behavioural and pharmacological interventions is of particular concern for behaviours such as smoking cessation. There are two types of interventions available to help smokers to quit: 1) pharmacological

interventions, such as nicotine replacement therapy, varenicline, and bupropion; and 2) behavioural support interventions, which involve discussion and activities aimed at maximising the smokers' motivation to quit whilst facilitating relapse prevention and coping (West & Stapleton, 2008). There is good evidence for the effectiveness of both types of interventions (Hajek, Stead, West, Jarvis, & Lancaster, 2009; Lancaster & Stead, 2005a, 2005b; Stead & T. Lancaster, 2012; Stead et al., 2013; Stead & Lancaster, 2005; Stead & Lancaster, 2012a, 2012b; Stead et al., 2012; Stead et al., 2006; Stead, Perera, & Lancaster, 2007), and both interventions are increasingly being delivered in practice as part of routine healthcare provision in numerous high- and middle-income countries (Pine-Abata et al., 2013). In the UK, both types of interventions have been implemented in clinical practice, and are widely available via a network of 152 NHS Stop Smoking Services (Bauld et al., 2010). Given the demonstrated effectiveness of both types of interventions, it is imperative that both interventions are equally well-specified and reported, in a clear and comprehensive manner, in order to minimise any potential discrepancies in Stop Smoking Practitioners' confidence for delivering both interventions in clinical practice.

The extent to which the reporting limitations discussed above apply to smoking cessation behavioural support interventions has not yet been systematically examined. This study therefore aimed to investigate reporting of intervention content in published trials of behavioural support interventions for smoking cessation. The recent development of a comprehensive, theory-linked taxonomy of BCTs has provided a reliable method by which the content of behavioural support interventions may be clearly specified in terms of component BCTs (Lorencatto, West, & Michie, 2012; Michie, Churchill, et al., 2011; West et al., 2011; West, Walia, et al., 2010). Each BCT is defined using consistent terminology and is classified hierarchically according to one of

four behaviour change functions (Michie, Hyder, et al., 2011). This study aimed to apply the taxonomy as a coding framework to compare the number and type of BCTs present in published reports of behavioural support trials to those BCTs included in the corresponding intervention protocols. Since advances in technology and online publishing, opportunities for providing additional information and detail via online supplementary material facilities have increasingly become available; this study therefore also examined change in the reporting of intervention content over recent years.

3.1.1. Aims and Objectives

The specific objectives of this study were to:

1. Assess the extent to which BCTs featured in trial protocols of smoking cessation behavioural support interventions are adequately reported in published trial reports.
2. Examine whether specific types of BCTs are more likely to be omitted from published reports than others.
3. Assess whether the adequacy of published reporting of intervention content has improved over time.

3.2. Methods

Study Design

This secondary data analysis compared the content, in terms of component BCTs, of intervention protocols to that of corresponding published trial reports of smoking cessation behavioural support interventions.

Sample

A total of 152 RCTs of smoking cessation behavioural support interventions were identified from three Cochrane Reviews (Lancaster & Stead, 2005a; Stead & Lancaster, 2005; Stead et al., 2006), and one systematic review (Banham & Gilbody, 2010). Of these, 27 were trials of one-to-one smoking cessation behavioural support (Lancaster & Stead, 2005a), 55 of group-based support (Stead & Lancaster, 2005), 62 of telephone-based support (Stead et al., 2006), and 8 of specialist mental health support (Banham & Gilbody, 2010).

Procedure

Authors of the trials were contacted on up to three separate occasions via e-mail requesting a copy of the corresponding trial protocol or any additional available documents that provided further information on the content of the intervention. For those trials for which a protocol was received, a copy of the corresponding published trial report was obtained. The descriptions of intervention content in each trial's protocol and published report were coded into component BCTs using an established taxonomy of 43 BCTs as a coding framework to guide identification and categorisation of featured BCTs (Michie, Hyder, et al., 2011). Each trial's protocol and published report was coded independently by at least two of three health psychology researchers, all of whom had extensive experience of applying the taxonomy of smoking cessation BCTs to

specify intervention content. If coders identified the same BCT within a section of text, agreement was registered. Where one coder identified a BCT and the other did not, or a different BCT was identified, disagreement was registered. If an instance arose that could not be coded by a BCT label from the taxonomy, this was identified as a potential new BCT. Discrepancies were resolved through discussion or consultation with a behaviour change expert.

Analyses

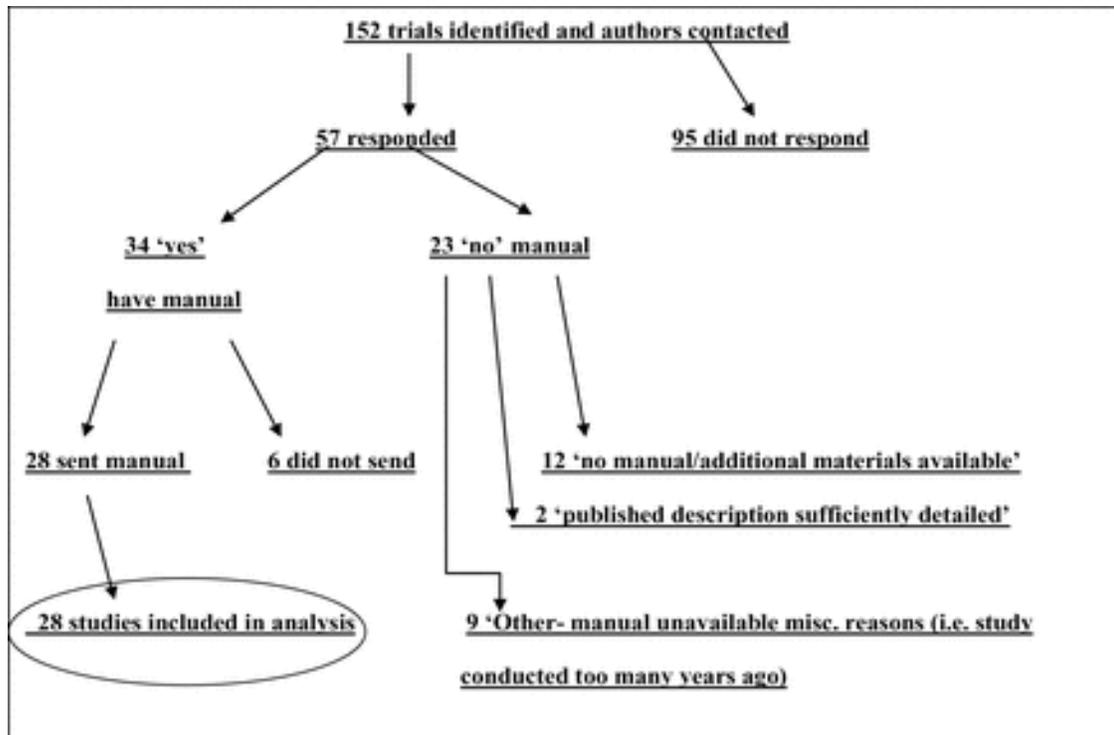
Inter-rater coding reliability was assessed using percentage agreement rather than Cohen's Kappa. Given our high number of available categories (i.e. 43 BCTs), the probability of selecting a particular BCT code by chance is low. As Kappa corrects for chance agreement among multiple coders, use of Kappa is likely to underestimate reliability (Steinijans, Diletti, Bomches, Greis, & Solleder, 1997).

To assess the comprehensiveness of reporting across trials, the difference between the number of BCTs identified in the trial protocol and the number of BCTs identified in the corresponding published report was assessed using a paired-samples t-test. The association between the number of BCTs originally included in the protocol and the percentage of BCTs subsequently reported in trial reports was assessed using a Pearson correlation. To establish whether particular types of BCTs were under-reported, the above analyses were repeated according to each of the four behaviour change functions outlined by the taxonomy: a) boost motivation, b) maximise self-regulatory capacity and skill, c) promote adjunctive activities, and d) general aspects of the interaction (Michie, Hyder, et al., 2011). For all BCTs originally included in at least one trial's protocol, the proportion of corresponding published reports in which the BCT was omitted from the intervention description was examined to establish which specific BCTs were the most frequently omitted. Lastly, to assess whether adequacy of intervention reporting has improved

over time, the association between year of trial publication and the percentage of BCTs in intervention protocols that were also subsequently reported in published trial descriptions was assessed by means of a pearson correlation.

3.3. Results

Figure 7. Response rate and the number of trials providing intervention protocols and therefore included in present analysis.



Of the 152 trial authors contacted, 57 responded (37.5%). Of these, 28 sent a copy of their trial protocol (49.1% of responding authors; 18.4% of all authors contacted) (Figure 7). Trials for which protocols were received were published between 1992 and 2008. The final sample therefore included in the present analysis was 28 trials.

Coding inter-rater reliability across trials was high (86.4% agreement), with all discrepancies easily resolved through discussion and no new BCTs identified in addition to those already

included in the taxonomy. Protocols contained on average 28 BCTs per trial (SD 17.2, range: 5-56), whereas corresponding published trial descriptions contained on average only 12 BCTs per trial (SD 6.08, range: 3-26), that is, an average of 44% of protocol BCTs (range: 13% to 100%) (Table 4, Figure 8). This difference was significant [$t(27) = -5.74, p < .001$]. Trial protocols that originally included a greater number of BCTs were significantly associated with a lower percentage of subsequent reporting of BCTs in the trial report ($r = -0.71, p < .001$) (Table 4). There was also no significant correlation between the year in which a trial was published and the number of BCTs in the intervention protocol that were also reported in subsequent published descriptions ($r = -.01, \text{non-significant}$) (Table 4, Figure 8).

Figure 8. The percentage of BCTs included in the original trial protocol that were subsequently reported in the corresponding trial report, presented by year of trial publication.

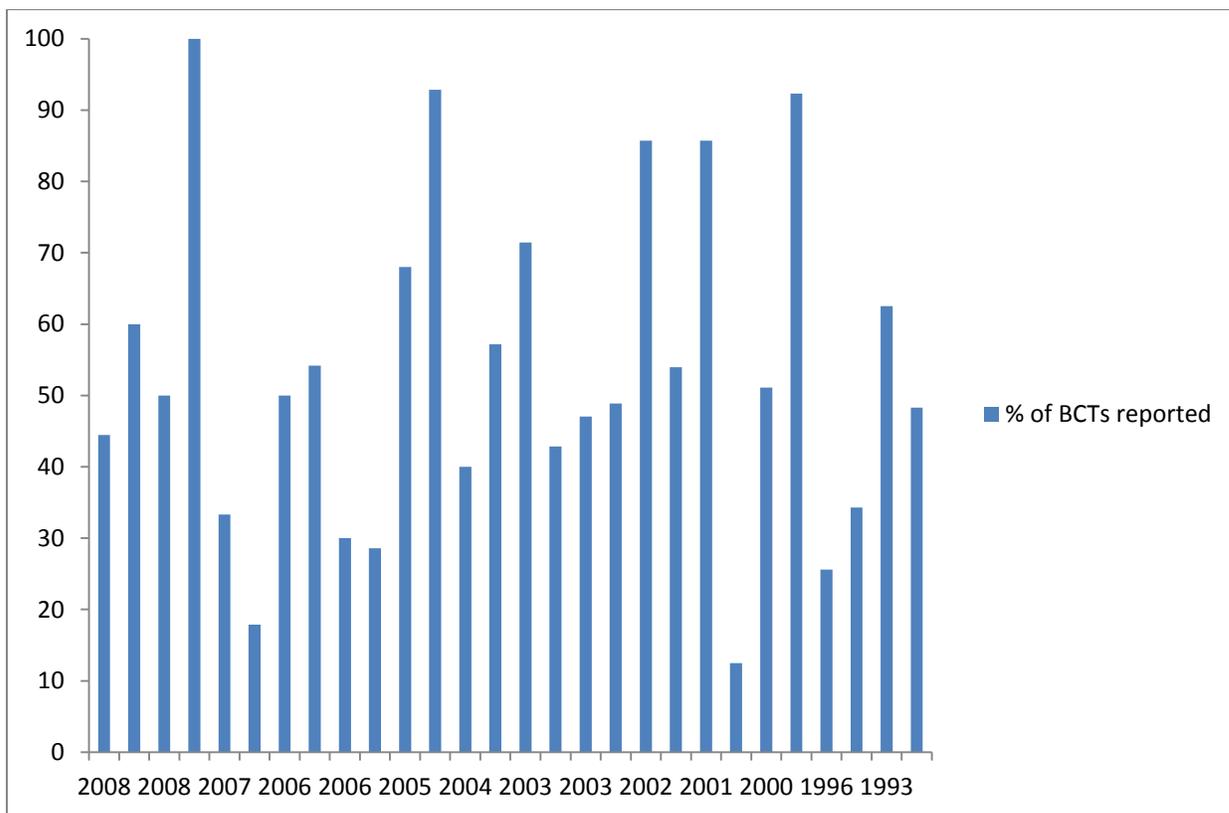


Table 4. Comparison of the Number of BCTs reported in published intervention descriptions compared with corresponding intervention protocols

Trial	Total BCTs in published descriptions	Total BCTs in protocol	Percentage of BCTs in protocol reported in subsequent published description
George et al. (2008)	20	45	44.44
Holmes-Rovner et al. (2008)	9	15	60
McCarthy et al. (2008)	17	34	50
Aveyard et al. (2007)	5	5	100
Ebbert et al. (2007)	7	21	33.33
Evins et al. (2007)	10	56	17.86
Ahluwalia et al. (2006)	11	22	50
Baker et al. (2006)	26	48	54.17
Duffy et al. (2006)	12	40	30
Evins et al. (2005)	16	56	28.57
Hennrikus et al. (2005)	17	25	68
McClure et al. (2005)	13	14	92.86
Katz et al. (2004)	4	10	40
Rabius et al. (2004)	12	21	57.15
Borland et al. (2003)	5	7	71.43
Molyneux et al. (2003)	3	7	42.86
Simon et al. (2003)	8	17	47.06
George et al. (2002)	22	45	48.89
Hennrikus et al. (2002)	6	7	85.71
Alterman et al. (2001)	9	17	53.94
Borland et al.	6	7	85.71

Trial	Total BCTs in published descriptions	Total BCTs in protocol	Percentage of BCTs in protocol reported in subsequent published description
(2001)			
Evins et al. (2001)	7	56	12.5
George et al. (2000)	23	45	51.11
Simon et al. (1997)	12	13	92.31
Zhu et al. (1996)	11	43	25.58
Jorenby et al. (1995)	12	35	34.29
McFall et al. (1993)	5	8	62.5
Ockene et al. (1992)	14	29	48.28

The same pattern of results was observed for BCTs across the four behaviour change functions, with significantly more BCTs included in the trial protocol than in the published reports (Table 5).

Table 5. Average number of BCTs identified in published trial reports compared with the corresponding trial protocol, presented by behaviour change function.

Behavior change function	Average number of BCTs in published report	Average number of BCTs in trial protocol	Average number of BCTs omitted	Significance of difference
Boost motivation	2.39 (<i>SD</i> 1.44), range: 0–5	6.42 (<i>SD</i> 5.00), range: 1–16	4.04	$t(27) = -4.72, p < .001$
Maximize self-regulatory capacity/skills	3.10 (<i>SD</i> 2.48), range: 0–8	8.17 (<i>SD</i> 4.75), range: 0–15	5.07	$t(20) = 5.08, p < .001$
Promote adjuvant activities	1.19 (<i>SD</i> 1.24), range: 0–4	2 (<i>SD</i> 1.94), range: 0–5	0.81	$t(20) = 2.65, p < .01$
General aspects of the role/interaction	5.47 (<i>SD</i> 2.20), range: 2–9	10.29 (<i>SD</i> 7.36), range: 3–22	4.82	$t(20) = 3.55, p < .005$

The BCTs identified in the intervention protocols that were most frequently omitted from published reports included techniques such as: ‘provide normative information on other smokers’ behaviours and experiences (included in 15 protocols; omitted from 100% of corresponding published reports),’ ‘explain expectations regarding the treatment programme (n=13 protocols; 100% omission),’ and ‘summarise information/ confirm client decisions (n=10 protocols; 100% omission)’ (Table 6).

Table 6. BCTs omitted from published intervention descriptions, ranked by frequency of omission

BCT	Number of manuals specified in	Percent of corresponding trial reports omitted from
BM5: provide normative information on other's experiences	15	100
RD2: emphasize choice	1	100
RC3: explain the purposes of CO monitoring	3	100
RC4: explain expectations regarding the treatment program	13	100
RC9: summarize information/confirm client decisions	10	100
GBM1: encourage group discussions	6	100
GBM2: encourage group tasks that promote interaction and/or bonding	6	100
GBM7: communicate group member identities	5	100
GRI1: screen suitability for group-based support	4	100
GRC2: discuss maintenance support	2	100
GRC1: explain group support	6	100
GA1: implement a buddy system	1	100
GA3: facilitate choice of medications in the group context	1	100
GBM6: encourage clients to make a public promise (contract with group members)	1	100
GBM9: report on missing members	1	100
BM13: create or reinforce negative associations	1	100
BS16: promote self-reward	2	100
BS15: promote behavioral substitution	3	100
RI8: assess level of social support	1	100
RI9: explain how tobacco dependence develops	12	92
BS13: advise on methods of weight control	11	91
BS12: facilitate restructuring of social life	10	90
BM8: strengthen ex-smoker identity	8	88
RC10: provide reassurance	14	86
BM6: prompt commitment from the client there and then	6	83
RC6: provide information on withdrawal symptoms	12	83

BCT	Number of manuals specified in	Percent of corresponding trial reports omitted from
BS14: teach relaxation techniques	17	82
BS6: prompt self-recording	14	79
BS11: advise on avoidance of cues for smoking	14	79
RC2: elicit and answer questions	9	78
BS9: set graded tasks	9	78
BM7: provide rewards contingent on effort or progress	13	77
BS5: prompt review of set goals	12	75
A4: ask about experiences of stop-smoking medication that the smoker is using	8	75
RI6: assess number of contacts who smoke	8	75
BM14: distract from motivation to engage in behavior	4	75
BS8: advise on environmental restructuring	15	73
RC1: build rapport	11	73
BM4: provide rewards contingent on successfully stopping smoking	10	70
BS10: advise on conserving mental resources	9	67
A3: adopt appropriate local procedures to enable clients to obtain free medication	3	67
BM3: provide feedback on current behavior and progress	9	67
BM10: identify reasons for wanting and not wanting to stop smoking	3	67
BS7: advise on changing routines	11	64
A2: facilitate use of social support	13	62
RC8: elicit client views	10	60
BM9: identify reasons for wanting and not wanting to stop smoking	17	59
RI7: assess attitudes toward smoking	7	57
RD1: tailor interactions appropriately	16	50
RC7: reflective listening	2	50
RI4: assess withdrawal symptoms	8	50
BM12: motivational interviewing	11	45
BS3: action planning/develop treatment plan	20	45
BM1: provide information on the consequences of smoking and smoking cessation	23	43
BS1: barrier identification and problem solving	20	40
BS2: relapse prevention and coping	25	40

BCT	Number of manuals specified in	Percent of corresponding trial reports omitted from
A5: give options for additional/later support	10	40
RI3: assess past history of quit attempts	19	37
BM2: boost motivation and self-efficacy	16	31
RI5: assess nicotine dependence	13	31
A1: advise on stop-smoking medications	17	30
RC5: offer/direct toward appropriate written materials	25	28
BS4: facilitate goal setting	21	24
RI10: assess physiological and mental functioning	9	22
RI1: assess current and past smoking behavior	27	15
RI2: assess current readiness and ability to quit	18	11
BM11: measure CO	6	0

3.4. Discussion

Published descriptions of behavioural support interventions for smoking cessation typically mention fewer than half of the BCTs specified in trial protocols; with up to 93% of BCTs included in the original intervention protocol failing to feature in subsequent published reports. Less than a fifth of trials examined reported at least 80% of the protocol's content in published trial reports, highlighting that a majority of trials did not fully or transparently report the original trial content. This deficit in reporting was demonstrated across different types of BCTs serving four behaviour change functions (Michie, Hyder, et al., 2011). Moreover, under-reporting was observed equally for BCTs that may be considered unique intervention components, specifically pertinent to smoking cessation behavioural support (i.e. strengthen ex-smoker identity 88%), as well as BCTs classifiable as more generic, wider counselling skills (i.e. provide reassurance 86%). These findings therefore suggest that there is no systematic pattern in the omission of specific types of BCTs when reporting intervention content.

An association between the number of BCTs found in protocols and the degree of subsequent underreporting was observed, with protocols containing more BCTs being more likely to report a smaller number of these in published reports. This finding will in part be an artefact of the fact that this analysis formed part of the calculation of underreporting; that is, the number of BCTs found in protocols formed the denominator for the calculated value. However, if the association reflects a genuine phenomenon, it may reflect limited journal publishing space, which would preclude detailed and complete reporting of more complex, multi-component intervention protocols. It may also be easier to report simpler intervention processes comprising fewer components. Another explanation is that larger intervention protocols may potentially contain more generic BCTs (i.e. 'eliciting and answering questions' or 'reflective listening') that authors

do not deem necessary to report in published descriptions. However this is unlikely as generic BCTs were reported to the same extent as more specific or unique BCTs.

The under-reporting for smoking cessation behavioural support interventions is consistent with findings from other areas of behaviour change (Dane & Schneider, 1998; Glasziou et al., 2008; Gresham et al., 1993; Michie et al., 2009; Moncher & Prinz, 1991; Odom et al., 2003). It does not conform to the CONSORT standard or other reporting guidelines (Boutron et al., 2008; Davidson et al., 2003; Des Jarlais et al., 2004; Moher et al., 2001). It is early days in determining how far these guidelines, the introduction of online supplementary publishing facilities and research such as this have improved reporting practice. Nonetheless, the present findings illustrate that no significant patterns of improvement in reporting are evident within the time period examined (1992-2008).

Poor reporting of intervention content has a number of implications. It undermines attempts to replicate an intervention as limited descriptions of intervention content are likely to result in content being replicated with poor fidelity. Secondly, it may impede optimal implementation of interventions in practice, as evidence suggests clinical guidelines and interventions are more readily introduced in a cost-effective manner when effective core components are clearly specified and reported (Michie, Fixsen, et al., 2009; Michie & Johnston, 2004). This may be one of the reasons why interventions with demonstrated effectiveness fail to achieve desired outcomes in practice. As behavioural interventions with demonstrated effectiveness in research become increasingly implemented in routine healthcare (Pine-Abata et al., 2013), it is important to ensure that their content is comprehensively translated into that of service treatment manuals.

Before the availability of electronic supplements to journal articles, the opportunity to report intervention content in published reports was restricted by the pressure faced by journal editors and authors to keep journal articles within strict word limits. However, a growing number of journals offer facilities to publish supplementary materials electronically. Indeed, the journals *Implementation Science* and *Addiction* now require all articles involving behavioural interventions to make the intervention protocols of trials publically available in supplementary files or other permanent records (Michie & Abraham, 2008; West, 2008). It is hoped that such policies will become universal.

The taxonomy of smoking cessation BCTs represents an efficient and consistent method of reporting intervention components, with clearly defined labels for individual BCTs that may be used as a shorthand common language when specifying and reporting the content of interventions (Michie, Hyder, et al., 2011). Widespread use of BCT labels from the taxonomy to describe intervention content when preparing intervention reports will promote consistency in the way in which intervention components are labelled across different interventions, which would in turn support evidence synthesis by facilitating comparisons of content across interventions. To improve the scientific study of behavioural interventions there should be clear and consistent identification and definition of intervention components in all stages of research, from early design of the intervention content and program through to the corresponding trial protocol, subsequent report and final dissemination (Michie et al., 2009).

One of the limitations of this study was the low response rate to the request for intervention protocols and the relatively small number of protocols received, which resulted in a small sample size for analysis. Despite contacting trial authors on multiple, separate occasions, response rates did not notably increase. This illustrates the difficulty of obtaining more information on

intervention content, and underlines the need to develop methods to ensure greater access to intervention protocols or additional documentation. A separate, but complementary, issue concerns the actual delivery of intervention content. Specifying the content of interventions based on published reports and original trial protocols only provides insight into intended content; there is no guarantee that this content was actually delivered by the intervention providers or that this content was delivered well (Borrelli, 2011). To obtain a truly representative and accurate understanding of what comprised an intervention deemed to be effective it is necessary to assess and report fidelity and quality of delivery as well as intended content in trial protocols.

In summary, this study contributes to a growing body of evidence highlighting the limitations in the standards of reporting for interventions to change health-related behaviours. Potentially the results of thousands of trials are not implemented successfully in practice as the corresponding published reports do not describe interventions in sufficient detail (Glasziou et al., 2010). Methods for addressing the deficit in reporting should be supported and extended, including reporting guidelines, journal policies, facilities for publishing supplementary materials, and taxonomies that provide agreed terminologies for describing intervention content.

3.5. Citation for the published peer-reviewed journal article for this study

Lorencatto, F., West, R., Stavri, Z., & Michie, S. (2013). How well is intervention content described in published reports of smoking cessation interventions? *Nicotine Tob Res*, *15*(7), 1273-1282.
doi:10.1093/ntr/nts266

For published-peer reviewed article see Appendix 11.

CHAPTER 4: Developing a method for specifying the components of smoking cessation behavioural support interventions in practice

4.1. Introduction

The previous two studies in this thesis have illustrated the reliability of the taxonomy as a coding framework for identifying and categorising the content of complex smoking cessation behavioural support interventions in terms of their component BCTs (Lorenatto et al., 2012; Lorenatto, West, Stavri, & Michie, 2013). On this basis, it was possible to reliably specify the components of a range of behavioural support interventions, including generic individual-, group- and telephone-based interventions (Lancaster & Stead, 2005a; Stead & Lancaster, 2005; Stead et al., 2006), as well as specialist behavioural support interventions for pregnancy and mental health (Banham & Gilbody, 2010; Lumley et al., 2009); thus illustrating the utility of the taxonomy as a reliable specification method for smoking cessation behavioural support interventions in a range of contexts.

The next step is to establish an effective and reliable method to monitor how these interventions are implemented, both in terms of quantity and quality of implementation (Durlak, 1998; Borrelli, 2011). Monitoring implementation is important throughout all stages of intervention development, evaluation, and delivery in applied settings (Craig et al., 2008). Arguably, it is easier to systematically monitor whether an intervention has been delivered as intended in research than in other settings. In research trials, interventions are usually controlled and standardized to a high extent, producing optimal conditions for intervention delivery. For example, randomized controlled trials are designed to minimise potential sources of bias; the settings, delivery procedures, intervention providers, and recipients are carefully selected and sampled to minimise unintended variability, ensuring that the intervention is thoroughly understood by both providers and recipients (Elliott & Mihalic, 2004). In such instances, it is more likely that the intervention delivered adheres to the intervention specified in the trial

protocol. Monitoring implementation in clinical practice is inherently more difficult and unpredictable as implementation of interventions in applied settings typically involves multiple intervention sites, providers, and recipients that are not purposively sampled to minimise variability. It is impossible to rigorously control clinical practice to the extent of research settings; therefore the probability of key intervention components being modified or inconsistently implemented is more likely (Durlak & DuPre, 2008; Elliott & Mihalic, 2004). Given this, it is important that methods for systematically monitoring implementation in clinical practice are established.

One of the recommended ‘gold standard’ methods for monitoring implementation is to objectively verify the delivery of a developed intervention by comparing audio- or video-recorded intervention sessions to pre-specifications in a trial protocol to ascertain whether intervention providers delivered the intended intervention, and to subsequently use these findings to accurately interpret and evaluate intervention outcomes (Borrelli, 2011). Two examples of this approach are from research trials evaluating behaviour change interventions to increase physical activity, and to reduce excessive alcohol consumption. The first examined audio-recorded sessions of an intervention aiming to increase physical activity amongst sedentary adults (ProActive trial), and assessed the extent to which the intervention facilitators displayed protocol-specified behaviours during four key sessions (Hardeman et al., 2008). These behaviours were 14 BCTs, such as ‘goal- setting’ and ‘use of rewards.’ Adherence to the delivery of these behaviours was low (~44%) and unrelated to change in predicted outcomes (Hardeman et al., 2008). The second study demonstrated the reliability and validity of a manual-based method for monitoring and rating the delivery of psychosocial interventions targeting excessive alcohol use (Tober, Clyne, Finnegan, Farrin, & Russell, 2008). This approach also involved coding recorded

sessions into component techniques using a coding framework with a priori-defined criteria to ascertain which intended intervention components were administered or absent from intervention sessions (Tober et al., 2008).

Such methods are currently lacking for smoking cessation behaviour change interventions, particularly in the context of clinical practice. Behavioural support interventions for smoking cessation have displayed heterogeneous outcomes in both research (Lancaster & Stead, 2005; Stead & Lancaster, 2005; Stead et al., 2006) and clinical practice (NHS Information Centre, 2011). If we are to understand what the ‘active ingredients’ are that contribute to the outcomes of effective smoking cessation behavioural support interventions, we need to look at what was actually delivered and how this varies, rather than what was ‘intended’ or ‘expected’ to be delivered. Indeed, descriptions of intervention content in trial protocols and service treatment manuals only represent ‘intended’ or ‘recommended’ practice and, as illustrated above, fidelity to these is rarely anywhere near 100% (Bellg et al., 2004; Hardeman et al., 2008; Tober et al., 2008). The taxonomy provides a reliable method for accurately specifying the content of interventions as described in trial protocols, treatment manuals, and published intervention reports (Lorenatto et al., 2012; Lorenatto et al., 2013; Michie, Churchill, & West, 2011; Michie, Hyder, Walia, & West, 2011; West, Evans, & Michie, 2011; West, Walia, Hyder, Shahab, & Michie, 2010). However, due to this demonstrated lack of fidelity to treatment manuals, these materials cannot be assumed to accurately reflect the content of interventions as delivered. It is therefore necessary to build upon this work to establish methods for assessing intervention content as delivered. The taxonomy could potentially serve as an effective and reliable tool for monitoring implementation if it can first be shown to be applied with demonstrable reliability to specify BCTs actually delivered in practice. Reliability refers to the

consistency with which the same techniques may be identified by independent researchers in intervention descriptions.

Identifying techniques delivered in practice is inherently different from identifying BCTs in protocols, in which techniques are described as single instructions (i.e. ‘set a quit date with the client’). In practice, techniques are embedded in conversations and clinical interactions between the Stop Smoking Practitioner and client (i.e. smoker), with intervention content potentially differing or being tailored according to the provider, context or client. Therefore, although the taxonomy holds the potential to serve as a reliable method for monitoring implementation, its reliability may be difficult to demonstrate in the clinical practice context. It is likely that the individuals responsible for monitoring implementation will also need to be trained to reliably apply such a method. The extent to which this is the case has not yet been formally examined.

4.1.1. Aims and Objectives

The aim of this study was to examine whether the taxonomy of smoking cessation BCTs may be developed as a method for reliably identifying and categorising component BCTs present in audio-recordings of behavioural support sessions delivered in practice by the NHS Stop Smoking Services. This is a necessary first step towards establishing a method to monitor ‘*what*’ or ‘*how much*’ of an intervention is delivered. A secondary aim of this study was to develop and evaluate the effectiveness of a manual for training novice coders in the application of the taxonomy.

4.2. Methods

Ethical approval

This study received ethical approval from the University College London departmental ethics committee (CEHP/2010A/015).

This study was conducted in two stages.

4.2.1. Stage 1: Applying and evaluating the taxonomy to specify BCTs delivered in behavioural support for smoking cessation

Sample and Materials

The original published taxonomy and list of competences (Michie, Churchill, et al., 2011; Michie, Hyder, et al., 2011), comprising 53 BCTs in total, was first expanded into a coding framework to be used for specifying BCTs in transcripts of audio-recorded behavioural support sessions. This was achieved by retaining the taxonomy's original structure, including all BCT codes, labels, definitions and hierarchical organisation of techniques according to behaviour change functions, and adding accompanying coding guidelines as well as additional columns for data extraction on the total frequency and location within transcripts that BCTs were identified (Appendix 1). The structure of the coding framework was informed by the frameworks utilised in previous studies aiming to specify component BCTs in recordings of delivered sessions for interventions targeting physical activity and excessive alcohol use (Hardeman et al., 2008; Tober et al., 2008).

Fifteen audio-recordings of routinely delivered behavioural support consultations were obtained. This sample size was selected to approximate the sample size used to establish the reliability of the originally developed taxonomy of BCTs, which was piloted on fourteen behavioural support

treatment manuals (Michie, Hyder, et al., 2011). Audio-recordings were obtained from three sources: the National Centre for Smoking Cessation and Training (NCSCT) ($n = 1$), a community pharmacy NHS Stop Smoking Service ($n = 5$), and a core NHS Stop Smoking Service employing specialist trained practitioners whose role is solely dedicated to delivering behavioural support ($n = 9$). The audio-recordings from the core NHS service and community pharmacy service were of one-to-one, consultations being delivered as part of routine clinical practice. Informed consent was obtained from both the practitioner and smoker prior to audio-recording the session. Sessions were recorded by the Stop Smoking Practitioners delivering the session, using a discrete audio-recording device. The audio-recordings obtained represented a mixture of sessions providing support to address the different stages of the quit attempt: pre-quit ($n = 7$ sessions), quit-day ($n = 4$), and post-quit ($n = 4$). The NCSCT audio-recording was of a series of training video-clips of simulated behavioural support consultations, scripted to illustrate the delivery of specific BCTs throughout the different aforementioned stages of the quit attempt. It thus served as ideal material on which to pilot the initial version of the taxonomy. All audio-recordings were fully anonymised and transcribed verbatim.

Procedure and Analysis

Transcripts were coded in three separate coding waves in the following order: 1) NCSCT transcript, 2) NHS community pharmacy service transcripts, and 3) core NHS Stop Smoking Service transcripts. Each transcript was coded independently by at least two of three health psychology researchers with prior coding experience using the taxonomy. Using the taxonomy coding framework, coders identified and categorised BCTs embedded within the practitioner's speech and assigned BCTs labels from the taxonomy where appropriate. Only the practitioner's dialogue was examined in order to evaluate just what was *delivered* to the client. The number of

transcripts each BCT was identified in as well as the frequency with which each BCT was identified within *and* across transcripts was examined. Specific instances of BCT use were extracted as exemplary quotes.

After each coding wave, inter-rater reliability was assessed between pairs of coders using percentage agreement. If coders identified the same BCT within a section of text, agreement was registered. Where two coders identified a BCT and the other not, or a different BCT was identified, disagreement was registered. If an instance arose in which no BCT label from the taxonomy suitably described the support being delivered, the coders recorded and discussed the instance as a potential identification of a new technique. Discrepancies were resolved through discussion or consultation with a behaviour change expert. Percentage agreement was used rather than Cohen's Kappa as the latter corrects for potential chance agreement amongst multiple coders. Given our high number of available categories (i.e. 53 BCTs), the probability of chance-selecting a particular BCT code is low, and use of Kappa therefore produces a conservative estimate of reliability (Steinijans, Diletti, Bomches, Greis, & Solleder, 1997). Furthermore, the items being coded (i.e. sentences with transcripts) were not mutually exclusive, as multiple BCTs may be present within a single sentence. Lastly, BCTs may be delivered more than once in a session and therefore be identified in different sections within the same transcript, with coders potentially agreeing on one instance of BCT identification but not the other. This in turn does not allow a global present/absent rating for each BCT over the entire transcript, which is required to calculate kappa. Therefore percentage agreement represented the best suited reliability assessment method for the present analyses.

Following Wave 1 of piloting on the NCSCT transcripts, issues emerging from the reliability discussions were used to identify and inform potential adaptations to the taxonomy in order to

improve the reliability of the taxonomy when applied to these materials, and to also simplify coding procedures where possible. The adapted taxonomy framework was then re-piloted in Waves 2 and 3, and reliability reassessed and discussed, in a cyclical and iterative process until high reliability was consistently achieved (i.e. at least 75% agreement) (Popping, 1988).

4.2.2. Stage 2: Development and evaluation of a BCT coding training manual

Sample and Materials

Existing manuals providing guidelines and instructions for coding the content of behaviour change interventions in other behavioural domains (Hardeman et al., 2008; Tober et al., 2008) were used by researchers with extensive coding experience to inform the development of a manual for training new coders to apply the taxonomy to specify the content of smoking cessation behavioural support interventions. The manual contained two sections: a) a brief background introduction to smoking cessation, behavioural support, and taxonomy methodology; and b) an introduction to the taxonomy coding framework (i.e. developed in Stage 1 of the present study), with accompanying detailed coding instructions, guidelines, helpful tips, plus four practice exercises allowing trainees to familiarise themselves with individual BCTs included in the taxonomy. The manual also contained excerpts from transcripts of audio-recorded behavioural support sessions delivered in clinical practice, which trainees used to practice identifying and categorising delivered BCTs using the taxonomy.

To evaluate the training, a 13-item questionnaire assessing trainees' self-perceived coding competence on a scale ranging from one (*not at all confident*) to five (*highly confident*) was developed (see items in Table 9). Before training, trainees completed the competence questionnaire and coded a transcript of a behavioural support session using the taxonomy coding

framework. This exercise was subsequently repeated post-training, using a second transcript. No feedback was given to trainees about their performance following the pre-training exercise. The transcripts used in the pre/post training exercises were purposively sampled so that they were matched for the number of BCTs they included. Administration of the transcripts for the coding exercises was counterbalanced. Both transcripts were of behavioural support sessions delivered by a specialist behavioural support service, and were coded by at least two experienced researchers, and reliability assessed, in Coding Wave 3 of Stage 1 in the present study. The BCT codes agreed upon by the experienced coders in Stage 1 were taken to represent a ‘gold standard’ and used as the answer key for the coding exercise. The BCTs identified by trainees were compared against BCTs in the gold standard answer key and inter-rater reliability assessed. Trainee demographics were also recorded.

Participants

The training was administered to ten trainees, purposively sampled to contain an equal number of research health psychologists ($n=5$) and non-psychologist practitioners (e.g. tobacco program delivery managers, project coordinators) ($n=5$).

Procedure

Trainees were sent the coding competence questionnaire and pre-training coding exercise to complete one week prior to attending a coding training workshop. The workshop was delivered by two experienced health psychology researchers who developed the training manual and coded the materials in Stage 1. The workshop lasted approximately three hours, during which the trainers presented the core content of the manual and trainees completed the four practice exercises and discussed answers with a partner, then as a group. Throughout, the trainers addressed any emerging questions or issues.

Upon completing the workshop, the trainees evaluated the course on a rating scale from one (*poor*) to five (*excellent*) and provided written feedback about which parts of the course were most and least useful. Within one week post-training, trainees were required to complete the post-training coding exercise and competence questionnaire. Mean course ratings were calculated. Within-subject differences in perceived competence ratings pre- and post-training were evaluated using a paired samples t-test. Each trainee's coding results on the pre/post training coding exercises were compared against the relevant set of agreed codes (i.e. the 'gold standard') and percentage agreement assessed. Discrepancies between agreement levels pre- and post-training were examined for each trainee and average percentage improvement calculated across trainees.

4.3. Results

4.3.1. Stage 1: Applying and evaluating the taxonomy to code behavioural support in practice

Coding Wave 1: NCSCT training video transcript

Of the 53 BCTs originally included in the taxonomy, 42 (79.3%) were reliably identified and categorised at least once within the NCSCT transcript (See Appendix 2). Inter-rater reliability across transcripts was high (93.4% agreement). All discrepancies were easily resolved through discussion. No new BCTs were identified or any major theoretical or structural problems with the taxonomy. Three minor adaptations to the taxonomy were proposed: a) reduce the number of items in the framework by merging typically co-occurring and conceptually related BCTs, and b) enhance clarity and facilitate distinction between BCTs by refining existing BCT definitions and labels, or c) creating definitions where previously absent. A full list of adaptations is available in Appendix 3, and summary examples of each in Appendix 4. The refined taxonomy comprised 40 BCTs (see Table 7 for BCTs included in revised taxonomy).

Table 7. Results from coding Waves 2 and 3, including total number of community and core NHS Service (SSS) transcripts each BCT was identified in, plus the total number of citations per BCT.

BCT Label	BCT Code	BCT Description	CORE NHS SSS		COMMUNITY PHARMACY SSS	
			Total No. of transcripts featured in Max n=9	Total No. Citations across sessions	Total No. of transcripts featured in Max n=5	Total No. Citations across sessions
‘BM’ Specific focus on behaviour (B) and addressing motivation (M)’						
BM1	Provide information on the health consequences of smoking and smoking cessation	Give, or make more salient, information about the physical/health harms caused by smoking and the benefits of stopping; distinguish between the harms from smoking and nicotine; debunk myths about low tar and own-roll cigarettes.	4	6	3	9
BM2	Boost motivation and self-efficacy	Give encouragement and bolster confidence in ability to stop. Can include telling the person that they can successfully stop smoking, arguing against self-doubts and asserting that they can and will succeed.	9	84	5	2
BM3	Provide feedback on current behaviour and progress	Give feedback arising from assessment of current self-reported or objectively monitored behaviour (e.g. expired-are CO) and/or progress towards becoming a permanent non-smoker.	9	68	3	13
BM4	Provide rewards contingent on not smoking	Give praise or rewards if the person has not smoked.	5	9	0	0
BM5	Provide normative information about others’ behaviour and experiences	Involves providing information about how the smoker’s experience compares with that of other smokers who are trying to quit, as to indicate that a particular behaviour or sequence of behaviours are	9	34	3	7

		common, or uncommon, amongst other smokers trying to quit.				
BM6	Prompt commitment from the client there and then	Encourage the smoker to affirm or reaffirm a strong commitment to start, continue or restart the quit attempt.	2	5	0	0
BM7	Provide rewards contingent on effort or progress	Give praise or other rewards for the effort the smoker is making in relation to smoking cessation and if the smoker has engaged in activities that aid cessation, such as correct medication use.	6	10	0	0
BM8	Strengthen ex-smoker identity	Explain the importance of regarding smoking that is 'not an option,' including the 'not a puff' rule, and construct a new identity as someone who 'used to smoke'	5	14	1	1
BM9	Facilitate identification of reasons for wanting and not wanting to stop smoking	Help the smoker to arrive at a clear understanding of his or her feelings about stopping smoking, why it is important to stop and any conflicting motivations.	7	15	3	2
BM10	Explain the importance of abrupt cessation	Explain why it is better to stop abruptly rather than cut down gradually if at all possible.	3	3	0	0
BM11	Measure CO and explain the purposes of CO monitoring	Measure expired- air carbon monoxide concentration and explain to the smoker the reasons for measuring CO at different time points (e.g. before and after the quit date)	7	47	2	4
BM12	Conduct motivational interviewing	Adopt a formal motivational interviewing protocol	0	0	0	0

'BS' Specific focus on behaviour (B) and maximising self-regulatory capacity/skills (S)

BS1	Facilitate barrier identification and problem solving	Help the smoker identify general barriers that might make it harder to stay off cigarettes (e.g. susceptibility to cigarettes). Help the smoker develop general ways of addressing and overcoming these, and increasing facilitators (e.g. by generating alternative	5	19	0	0
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		courses of action and pros and cons of each and weighing them up)				
BS2	Facilitate relapse prevention and coping	Help the smoker understand how lapses occur and how they lead to relapse. Plan how to maintain behaviour that has changed, by helping identify in advance situations in which the changed behaviour may not be maintained, and develop specific strategies for preventing lapses or avoiding lapses turning into relapse.	5	21	0	0
BS3	Facilitate action planning/develop a treatment plan	Work with the smoker to encourage generation of a clear, detailed quit plan including preparations for the quit attempt (e.g. obtaining medication).	6	19	1	2
BS4	Facilitate goal setting	Help the smoker set a quit date and goals that support the aim of remaining abstinent	6	42	1	4
BS5	Prompt review of set goals	Review how far the smoker has achieved the main goal of abstinence and any other goals that are supportive of it (e.g. putting in place plans to avoid triggers). In most cases this will follow previous goal setting and an attempt to act on those goals, followed by a version of revision or readjustment of goals and/or means to attain them.	4	7	2	1
BS6	Prompt self-recording	Help the smoker establish a routine of recording potentially useful information (e.g. situations or times when urges are strong and less strong)	1	1	0	0
BS7	Advise on changing routine	Advise on ways of changing daily or weekly routines to minimize exposure to smoking cues	4	12	0	0
BS8	Advise on environmental restructuring	Advise on ways of changing the physical environment to minimize exposure to physical smoking cues (e.g. removing ashtrays from the house)	3	20	0	0
BS9	Set graded	Set small achievable goals	0	0	0	0

	tasks	where appropriate (e.g. take one day at a time)				
BS10	Advise on conserving mental resources	Advise on ways of minimizing stress and other demands on mental resources (activities that require mental effort)	4	5	0	0
BS11	Advise on avoiding social cues for smoking	Give specific advice on how to avoid being exposed to social cues for smoking (e.g. explaining to friends that you have stopped and asking them not to smoke around you)	7	22	0	0
BS12	Facilitate restructuring of social life	Advise on ways of changing social interactions so that they support rather than interfere with smoking cessation	4	15	1	1
BS13	Advise on methods of weight control	Advise on methods of weight control, including diet and/or exercise	1	1	0	0
BS14	Teach relaxation techniques	Teach specific relaxation techniques and how and when to apply them	0	0	0	0

Promoting adjuvant activities ‘A’ – including general aspects of the interaction focusing on delivery of the intervention

A1	Advise on stop smoking medication	Includes one or more of the following: - explaining the benefits of medication, safety, potential side-effects, contra-indications, how to use them most effectively, - advising on the most appropriate medication for the smoker - promoting effective use - explaining how to obtain medications, enacting the necessary procedures to ensure the smoker gets their medication easily and without charge where appropriate	9	179	3	60
A2	Advise on/facilitate use of social support	Advise on or facilitate development of social support from friends, relatives, colleagues or buddies.	2	6	0	0

A3	Ask about experiences of stop smoking medication that the smoker is currently using	Asses usage, side effects and benefits experienced of medication that the smoker is currently using.	7	38	0	0
A4	Give options for additional and later support	Give information about options for additional support where these are available (e.g. websites, self-help groups, telephone helpline)	5	12	3	2
<hr/>						
‘RC’ General aspects of the interaction (R) focusing on general communication (C)						
<hr/>						
RC1	Build general rapport	Establish a positive, friendly and professional relationship with the smoker and foster a sense that the smoker’s experiences are understood	9	46	5	10
RC2	General practitioner communication approaches	Communication that includes one or more of the following: eliciting and answering questions, using reflective listening, summarizing information, and confirming client decisions	9	311	5	78
RC3	Emphasise choice	Emphasise client choice within bounds of evidence based practice	4	12	1	0
RC4	Provide reassurance	Give general reassurance to the smoker that his/her experiences are normal and time limited, and provide positive expectations of success based on experience with other smokers in the same situation	9	94	5	20
RC5	Tailor interactions appropriately	Use relevant information from the client to tailor the behavioural support provided	4	6	0	0
RC6	Offer/direct towards appropriate written materials	Distinguish what are, and are not, appropriate written materials and offer/direct clients to these in ways that promote their effective use	4	7	0	1
RC7	Information gathering and assessment	Any information gathering that provides the practitioner with the knowledge needed from the client for appropriate behaviour change techniques to be delivered. Includes one or more of the following: - Assessing current	9	47	5	15

		and past smoking behaviour				
		<ul style="list-style-type: none"> - Assessing current readiness and ability to quit - Assessing past history of quit attempts - Assessing withdrawal symptoms - Assessing nicotine dependence - Assessing number of contacts who smoke - Assessing attitudes to smoking - Assessing level of social support - Assessing physiological and mental functioning 				
RC8	Explain how tobacco dependence develops	Give an explanation of the development of tobacco dependence and the effect of nicotine	4	12	2	8
RC9	Explain expectations regarding the treatment programme	Explain to the smoker the treatment programme, what it involves, the active ingredients, and what it requires of the smoker	7	24	3	6
RC10	Provide information on withdrawal symptoms	Describe to smokers what are and are not nicotine withdrawal symptoms, how common they are, how long they typically last, what causes them and what can be done to alleviate them.	4	20	0	0

Coding Wave 2: Community pharmacy transcripts- re-piloting of the revised taxonomy

Of the 40 BCTs in the revised taxonomy, 20 (50%) were identified at least once across community pharmacy session transcripts (Table 7). Each session lasted on average 5 minutes, 31 seconds (range= 2:50 – 7:53) and contained an average of 12 BCTs (range: 8 – 17). The most frequently featured BCTs (n=5 sessions) were: *'boost motivation,' 'build rapport,' 'general communication approaches,'* and *'information gathering and assessment,'* Of those delivered at least once, the least frequently delivered BCTs (n=1) were: *'strengthen ex-smoker identity,' 'action planning,' 'goal-setting,' 'facilitate restructuring of social life,'* and *'emphasize choice.'* Average inter-rater reliability for identifying the same BCTs in text using the revised taxonomy was high (78.4%). No additional BCTs or further potential adaptations to the taxonomy were identified.

Coding Wave 3: Core NHS Stop Smoking Service transcripts- re-piloting of the revised taxonomy.

Of the 40 BCTs in the revised taxonomy, 37 (92.5%) were identified at least once (see Table 7). Core NHS behavioural support sessions lasted on average 11 minutes, 49 seconds (range= 5:17-17:43), and contained on average 20 BCTs per session (range: 12 - 31) (See Table 7). Eight BCTs were featured in all sessions (n= 9), including: *'provide feedback on performance,'* and *'provide normative information on others' experiences.'* Of those identified at least once, the least frequently delivered BCTs were: *'prompt commitment from the client there and then (n= 2),' 'prompt self-recording (n=1),'* and *'advise on methods of weight control (n=1).'* Average inter-rater reliability across transcripts was high (95.7%), and no further proposed adaptations to the taxonomy or additional BCTs were identified. An illustration of the application of the

taxonomy to deconstruct and code an excerpt from a behavioural support session transcript into component BCTs is provided in Figure 9.

Figure 9. Example of the taxonomy of smoking cessation BCTs applied to code an excerpt from a transcript of a behavioural support session being delivered in a core NHS service. Identified BCT labels are presented in italics and brackets next to the relevant segment of text.

Practitioner (P): Exactly. And I think, you know, the important thing is that now both last week and this week you've come in and you've said you've had those really difficult moments but you didn't smoke [BM3- *Provide feedback on performance*] so you know, you should sort of be proud of that side of things [BM4- *Provide rewards contingent on not smoking*]

Client (C): Yeh, yeh, it's really strange, it is really strange. I'd have thought I would be more 'look at me'

P: Yeh

C: but I haven't got that enthusiasm

P: Maybe that's because you don't feel quite like you've.. Did I ask you that? No. That question about whether you've become a non-smoker or whether you feel like you're becoming a non-smoker. Maybe you don't feel like you have become a non-smoker yet [BM8- *Strengthen ex-smoker identity*] which is no bad thing, because it means you're not complacent about it and you're just still getting there [RC4- *Provide reassurance*]

C: Hmm

4.3.2. Stage 2: Development and Evaluation of a BCT Coding Training Manual

Trainee characteristics

Trainees had an average age of 29.3 years (range: 23-38). None had prior experience of coding. Five were health psychologists familiar with qualitative methodology and were aware of the original taxonomy; the other five had minimal familiarity with qualitative methods and had not heard of the taxonomy.

Coding performance pre/post training

Complete follow-up data on coding performance was obtained for eight trainees ($n=2$ missing). Before training, percentage agreement between trainees and the gold standard was, on average, 32.2% ['poor'; (Popping, 1988)], but improved significantly to 61.6% agreement ('good') post-training (Table 8). The average increase in reliability was 29.5% [$t(7) = -19.7, p < .001$]. There were no significant differences between the more experienced psychologists and less experienced trainees.

Table 8. Trainee coding inter-rater reliability pre- and post- training

Trainee ID (P= Psychologist; NP= Non- psychologist)	% agreement pre- training	% agreement post- training
1(P)	46.1%	70.1%
2 (P)	31.1%	58.6%
3 (P)	32.6%	62.8%
4 (P)	32.9%	63.4%
5(NP)	32.2%	58.1%
6 (NP)	23.8%	60%
7 (NP)	25.6%	57.4%
8 (NP)	32.11%	62.2

Self-perceived coding competence

Before training, average self-perceived coding competence was 2.39 (SD .026), equating to ‘low’ competence. Post-training, average ratings for all 13 items increased, with a mean rating of 3.74 (SD=.029) post-training (i.e. ‘moderate’ to ‘good’ competence). Improvements were statistically significant for all questionnaire items (Table 9).

Table 9. Average trainee ratings of self-perceived coding competence (from 1= ‘not at all confident’ to 5 =’highly confident’) pre-and post-training.

Questionnaire item	Mean Rating pre-training	Mean Rating post-training	Significance of difference
1. Identifying the components of a behaviour change intervention in smoking cessation	2.70	3.90	t(8)=-4.40 p<0.001
2. Clearly describing the components of a behaviour change intervention in smoking cessation	2.40	3.70	t(8)=-5.66 p<0.001
3. Categorising the components of a behaviour change intervention in smoking cessation	2.00	3.50	t(8)=-8.22 p<0.001
4. Using qualitative data analysis methods	2.30	3.20	t(8)=-3.41 p<0.005
5. Identifying the behaviour change techniques (BCTs) delivered during a behavioural support intervention for smoking cessation	2.40	4.10	t(8)=-5.77 p<0.001
6. Using a taxonomy of smoking cessation BCTs to label BCTs identified in a behavioural support session	2.30	4.10	t(8)=-4.88 p<0.001

7. Applying a coding framework based on a taxonomy of smoking cessation BCTs to identify and categorise BCTs	2.40	3.90	t(8)=-5.29 p<0.001
8. Conducting a content analysis of transcripts of audio-recorded behavioural support sessions	2.10	3.60	t(8)=-4.13 p<0.005
9. Describing what a BCT for smoking cessation is	3.00	4.00	t(8)=-4.40 p<0.05
10. Explaining the aims and components of behavioural support interventions for smoking cessation	2.50	3.70	t(8)=-3.77 p<0.005
11. Assessing how often different BCTs are used during a behavioural support session	2.30	3.80	t(8)=-4.91 p<0.001
12. Pointing out when a Stop Smoking Practitioner delivers a BCT	2.50	3.90	t(8)=-5.66 p<0.001
13. Deconstructing a health behaviour change intervention into its functional components (i.e. active ingredients)	2.20	3.20	T(8)=-4.63, p<0.05

Course evaluation

Seven trainees completed the course evaluation. The average course rating was 4.86 (SD=.23), equivalent to ‘excellent.’ The elements of the course most frequently cited as beneficial to training were the practice exercises ($n=6$) and group discussions ($n=4$).

4.4. Discussion

In this study, the extent to which the component BCTs of smoking cessation behavioural support interventions delivered in a clinical practice context could be reliably specified using an established taxonomy of smoking cessation BCTs was examined (Michie, Hyder, et al., 2011). Inter-rater reliability for consistently identifying and categorising the same BCTs within transcripts of audio-recorded behavioural support sessions using the taxonomy as a coding framework was consistently high (average= 88% agreement). This level of inter-rater agreement is similar to those achieved in previous studies applying the taxonomy to specify the content of published intervention descriptions, trial protocols, and NHS service treatment manuals into component BCTs (Lorenцatto et al., 2012; Lorenцatto et al., 2013; Michie, Churchill, et al., 2011; Michie, Hyder, et al., 2011; West et al., 2011; West et al., 2010). This finding therefore contributes to the growing body of evidence illustrating the reliability and versatility of the taxonomy methodological approach for specifying the content of complex behaviour change interventions delivered in both research and practice settings.

Establishing a method that is reliable for specifying the components of behavioural support interventions in both research and practice is an important first step towards counteracting the typically inconsistent and poor specification of the content of complex behaviour change interventions (Michie, Abraham, et al., 2011; Michie, Fixsen, Grimshaw, & Eccles, 2009). To our knowledge, this is the first attempt to systematically characterise the content of smoking cessation behavioural support delivered in practice in terms of individual techniques. This fulfils a necessary pre-requisite for establishing a reliable and systematic method for monitoring the implementation of interventions in practice. Moreover, this study also developed an effective training manual to train new, inexperienced coders from multidisciplinary backgrounds to

reliably apply the taxonomy to specify intervention content. To our knowledge, this manual is also the first of its kind to be formally evaluated and represents a feasible, easily administered approach to train future coders. This finding supports the feasibility and utility of the taxonomy as a method for reliably monitoring the implementation of behavioural support interventions.

Because the taxonomy has now demonstrated equivalent levels of reliability when applied to code both treatment manuals (Lorenцatto et al., 2012; Michie, Churchill, et al., 2011; West et al., 2011; West et al., 2010), and transcripts of practice sessions, this method can now potentially be used to systematically examine discrepancies between ‘intended’ or ‘recommended’ practice, and ‘actual practice;’ that is, to assess the fidelity of delivery of behavioural support interventions in practice. This will enable the systematic comparison of how practice varies across, as well as within, individual services, which may help to explain why interventions may not be effective in certain settings and why outcomes vary across services or providers. In addition, differences in practice according to practitioners may be examined. For example, in the current study, differences between community pharmacist and dedicated specialist practitioners were observed, with specialist practitioners delivering longer sessions that contained a greater average number of BCTs per session than those delivered by community pharmacists. Consequently, relevant practitioner training needs and aspects of service delivery requiring future improvement may be identified.

Applying the taxonomy to specify the components of behavioural support interventions in treatment manuals from the NHS services has enabled identification of BCTs significantly associated with improved four-week CO-validated and self-reported quit rates for individual- and group-based behavioural support interventions (West et al., 2011; West et al., 2010). This is an important step towards furthering our theoretical understanding of the active ingredients and

causal mechanisms contributing to effective outcomes of behavioural support interventions in practice settings. Having now established the reliability of the taxonomy to code actual practice, the repetition of such analyses using a representative sample of audio-recordings could help establish which BCTs that are actually delivered in practice are effective.

Limitations to this study include the small size and range of the sample of pilot transcripts examined. The extent to which this method may be reliably applied to a larger number of transcripts, or transcripts delivered in clinical contexts other than the English NHS Stop Smoking Services remains to be ascertained. In addition, given the on-going developments within BCT methodology research, the adapted taxonomy and training manual are likely to require future adaptation and revisions as new evidence emerges, new BCTs are identified, and the taxonomy is applied to new contexts or settings.

A further methodological feature that may be a limitation is that audio-recordings were used rather than video-recordings to examine delivered content. Compared to video-recordings, audio-recordings are more practical, time-efficient, economical, and less intrusive to obtain in clinical practice. Although video-taped consultations provide additional non-verbal content, with the exception of a few BCTs such as ‘building rapport,’ all of the BCTs within the taxonomy require some minimal degree of verbalization in order to be delivered and therefore can be coded on the basis of audio data. For example, it is necessary to *advise on* social support, *facilitate* problem solving or action planning, *elicit* client views, etc. Furthermore, this method enables the identification of *what* or *how much* is delivered; a separate question is *how well* BCTs are delivered. Methods to assess and quantify quality or competence in delivery of intervention components have been established in medicine (Salgado, Moles, Benrimoj, & Fernandez-Llimos, 2012) and cognitive behavioural therapy (Muse & McManus, 2013), and are emerging for health

behaviour change interventions (Farmer et al., 2012; Tober et al., 2008). However, we lack such a method for smoking cessation behavioural support. Establishing a comprehensive method for monitoring implementation of smoking cessation behavioural support interventions will therefore also require future development of methods to assess quality of delivery.

In conclusion, this study establishes the reliability and utility of the BCT taxonomy as a coding method for specifying the content of smoking cessation behavioural support interventions as delivered in practice. It provides a common language and reliable methodology for characterising the content of complex behaviour change interventions delivered in different formats, from treatment manuals to trial reports and transcripts of actual intervention sessions delivered in clinical practice. This method, including an effective BCT coding training manual, can be used in future research to further our understanding of how behavioural support interventions are delivered and can be improved, by applying it in a process evaluation to examine fidelity and quality of delivery.

4.5. Citation for published peer-reviewed journal article for this study:

Lorenatto, F., West, R., Seymour, N., & Michie, S. (2013). Developing a method for specifying the components of behavior change interventions in practice: The example of smoking cessation. *Journal of Consulting and Clinical Psychology, 81*(3), 528-544. doi: 10.1037/a0032106

For published-peer reviewed article see Appendix 11.

CHAPTER 5: Assessing Fidelity of Delivery of Smoking Cessation

Behavioural Support in Practice

5.1. Introduction

The previous studies in this thesis (Chapters 2-4) have demonstrated the utility of the taxonomy as a reliable framework for specifying the components of behavioural support interventions in published reports, manuals and transcripts of behavioural support interventions (Lorenatto, West, & Michie, 2012; Lorenatto, West, Seymour, & Michie, 2013; Lorenatto, West, Stavri, & Michie, 2013). The next step is to apply the taxonomy as a method for assessing implementation of smoking cessation behavioural support interventions in target settings (i.e. clinical practice).

The translation of evidence-based interventions into clinical practice is a complex, multi-stage procedure that is often slow, variable and unpredictable (Eccles et al., 2009; Grol & Grimshaw, 2003). For instance, behavioural support interventions for smoking cessation have been shown to be effective in numerous randomized trials (Lancaster & Stead, 2005; Stead & Lancaster, 2005; Stead, Perera, & Lancaster, 2006) and have subsequently been implemented widely in clinical practice (Pine-Abata et al., 2013). For example, implementation in the UK is via a network of 152 NHS Stop Smoking Services, which have demonstrated effectiveness in supporting smokers to quit (Bauld, Chesterman, Judge, Pound, & Coleman, 2003; Judge, Bauld, Chesterman, & Ferguson, 2005). However, outcomes of behavioural support interventions implemented in clinical practice are extremely heterogeneous; in 2011 the four-week quit rates across 152 NHS Stop Smoking Services ranged from 5% to 59% (NHS Information Centre 2011).

Methods are therefore needed to promote the consistent, systematic uptake of evidence-based behavior change interventions into routine practice in order to increase the likelihood of consistently achieving target outcomes (Eccles et al., 2009). Treatment manuals represent one potential vehicle by which the content of interventions with demonstrated effectiveness may be translated into the content of clinical practice (see Figure 4, Chapter 1). The term ‘treatment

manual' typically refers to structured, procedural books outlining the rationale and goals of an intervention, as well as the recommended content (i.e. behaviour change techniques/BCTs) to be delivered when administering an intervention (Wilson, 1996). Use of treatment manuals presents numerous advantages for clinical practice: they aid the dissemination and replication of interventions; help focus and structure the content of interventions that typically need to be delivered within strict time constraints alongside the competing demands of clinical practice; and facilitate the training and supervision of intervention providers to ensure they possess the necessary competences to effectively deliver an intervention (Wallace & von Ranson, 2011; Wilson, 1996). The recent increase in the pressure to employ treatment manuals has extended beyond controlled research trials into clinical practice (Wallace & von Ranson, 2011). Recent evidence has demonstrated that improved long-term treatment outcomes in an outpatient clinic were associated with the delivery of manual-based, empirically supported treatments (Cukrowicz et al., 2011).

Treatment manuals are widely used in the delivery of smoking cessation behavioural support interventions. In the UK, national guidelines outlining the recommended content and format of smoking cessation behavioural support sessions have been published (Croghan, 2011; West, McNeill, & Raw, 2000). These recommend that evidence-based guidelines should inform how behavioural support is delivered by the English NHS Stop Smoking Services. Most of these services have a treatment manual providing standardized guidance for Stop Smoking Practitioners regarding the specific content to be delivered in different types of behavioural support sessions (i.e. pre-quit, quit-day and post-quit). However, there is evidence that different practitioners delivering support within the same Stop Smoking Service, and therefore operating under the same treatment manual, have widely differing success rates (Brose, McEwen, & West,

2012). This raises an important question as to how far behavioural support is implemented according to specification in treatment manuals, and whether practitioners are adhering to, or deviating from, manual-based treatment specifications when delivering behavioural support sessions.

Examining the extent of implementation often involves conducting a ‘process evaluation,’ which typically consists of an assessment of intervention fidelity. Fidelity broadly refers to the extent to which interventions are delivered as intended (Bellg et al., 2004). A five-part conceptual framework of treatment fidelity has recently been developed that synthesizes and integrates previous models and conceptualizations of treatment fidelity (Borrelli, 2011; Borrelli et al., 2005). The first two parts concern the intervention development stage: (1) *design*, which involves factors to consider during intervention development, including specifying the theoretical rationale and components of an intervention, and (2) *training*, which involves verifying intervention providers are competent to deliver the intervention according to its original specification. Part (3), *delivery*, involves monitoring and improving the delivery of an intervention to ensure that it is delivered as intended, according to a priori specifications in treatment manuals. Parts (4) and (5), *receipt* and *enactment*, respectively concern first verifying intervention recipients understood the information provided during the intervention, and secondly, monitoring their ability to perform treatment-related cognitive strategies and/or behavioural skills (Borrelli, 2011; Borrelli et al., 2005).

Verifying fidelity is part of the ongoing assessment, monitoring and enhancement of the reliability and internal validity of an intervention (Bellg et al., 2004). For instance, it is essential for accurately interpreting intervention outcomes; intervention outcomes can only be confidently attributed to the intervention developed if it is first established that the intervention was

implemented in its entirety. If certain components are omitted from or added to the intervention during delivery, it is possible that it is these components that are responsible for changing behaviour, resulting in an unaccounted for loss or gain of intervention effects (Elliott & Mihalic, 2004). This in turn may result in effective interventions erroneously being discarded or ineffective interventions being used (Hardeman et al., 2008). Moreover, monitoring fidelity in early stages of implementation may allow steps to be taken to prevent more widespread and enduring deviations in implementation (Borrelli, 2011). Monitoring fidelity also aids theory testing, as verifying that theory-based intervention components are actually delivered supports any inferences regarding links between hypothesized mechanisms of action and intervention outcomes (Borrelli, 2011). Lastly, identifying variations in intervention delivery supports the identification of intervention provider training needs (Elliott & Mihalic, 2004).

Although the importance of examining intervention fidelity is widely recognized, literature reviews suggest that it is not frequently assessed, reported, or accounted for in analyses (Dane & Schneider, 1998; Dusenbury, Brannigan, Falco, & Hansen, 2003; Moncher & Prinz, 1991). Recommendations for methods to assess fidelity are widely available (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005), but these are rarely applied. Recently developed methods for assessing fidelity of delivery of interventions for physical activity (Hardeman et al., 2008) and excessive alcohol use (Tober, Clyne, Finnegan, Farrin, & Russell, 2008) use the recommended ‘gold standard’ strategy of objectively verifying delivery by comparing the content of recorded intervention sessions to pre-specified criteria, such as an intervention manual (Borrelli, 2011). In research studies where fidelity is assessed using such methods, it is often found that fidelity of delivery is poor, with on average less than 50% of manual-specified content found to be

routinely delivered in intervention sessions (Dane & Schneider, 1998; Durlak & DuPre, 2008; Dusenbury et al., 2003; Hardeman et al., 2008).

There are even fewer examples of fidelity assessments of health behaviour change interventions conducted in the context of clinical practice. Two studies have found fidelity of delivery of core intervention components to be low and inconsistent across counsellors in clinical practice (Dewing et al., 2013; Hatch-Maillette, Burlew, Turnbull, Robinson, & Calsyn, 2013). The first examined the fidelity of an evidence-based intervention for promoting adherence to antiretroviral medications delivered by lay counsellors in two clinics (Dewing et al., 2013), and the second measured the fidelity of delivery of a culturally adapted HIV prevention intervention for men in substance abuse treatment (Hatch-Maillette et al., 2013). Both studies objectively verified the delivery of manual-specified intervention components by examining counsellor performance in audio-recordings of intervention sessions, and found fidelity to be poor.

To my knowledge, only one study of smoking cessation behavioural support interventions has evaluated fidelity of delivery, and this was conducted in the context of a research trial (Collins et al., 2009). The study applied a standardized framework to evaluate adherence to treatment manuals by intervention providers (Waltz, Addis, Koerner, & Jacobson, 1993). Collins et al examined audio-recordings of group behavioural support sessions to establish whether four categories of intervention components were present in session transcripts: (1) unique and essential to the intervention; (2) not unique, but essential; (3) acceptable if delivered but not necessary; and (4) proscribed. Analysis of transcripts showed only partial therapist adherence to treatment manuals, with less than 100% adherence observed even for the components deemed to be unique and essential to the intervention (Collins et al., 2009).

If fidelity is observed to be poor in optimally controlled research trial conditions, it is likely to be even more variable in unpredictable clinical practice settings (Elliott & Mihalic, 2004). However, we currently lack methods and examples of strategies to assess the fidelity of smoking cessation behavioural support interventions delivered in the context of clinical practice. The recent development of a theory-linked taxonomy of 43 smoking cessation BCTs has provided a reliable method for specifying the content of behavioural support interventions in terms of their component BCTs (Michie, Hyder, Walia, & West, 2011). Each BCT has pre-specified criteria for its operationalization, is defined using clear terminology, and has a clear label that can be used to categorize and consistently report intervention components. The taxonomy has demonstrated reliability when applied to identify and characterize BCTs present in NHS Stop Smoking Service treatment manuals (Lorenцatto et al., 2012; Michie, Churchill, & West, 2011; West, Evans, & Michie, 2011; West, Walia, Hyder, Shahab, & Michie, 2010). It has since been demonstrated that the taxonomy may also be reliably applied to specify BCTs present in transcripts of audio-recorded behavioural support sessions delivered by NHS Stop Smoking Services in clinical practice (Lorenцatto, West, Seymour, et al., 2013). Treatment manuals represent ‘intended’ or ‘recommended’ practice, whereas transcripts of audio-recorded behavioural support sessions provide a means of observing ‘actual’ practice; the extent to which the taxonomy may therefore be applied as a framework for reliably comparing the content of ‘intended’ and ‘actual practice’, that is, to assess fidelity of delivery, has yet to be systematically examined.

5.1.1. Aims and Objectives

This study aimed to conduct a pilot evaluation of the BCT taxonomy as a method for investigating variations in the fidelity of delivery of smoking cessation behavioural support delivered by two NHS Stop Smoking Services. This will be achieved by comparing BCTs

specified in treatment manuals, against BCTs delivered in practice. Specifically, this study will investigate whether the taxonomy provides a reliable framework for assessing whether (i) manual-prescribed intervention components are delivered, and (ii) BCTs *not* specified in treatment manuals are delivered. Examining ‘additional’ delivered content is important as such content introduces further variability in practice and outcomes, and may either augment or detract from the delivery of manual-specified content. This study did not address the separate but associated question of *how* components are delivered, for example, in terms of quality or tailoring of delivery.

The specific objectives of this study were:

1. To evaluate a method for assessing fidelity of behavioural support for smoking cessation using a taxonomy of behavior change techniques (BCTs);
2. To assess using this method the fidelity of delivery of behavioural support in two English Stop-Smoking Services
3. To examine variation in fidelity according to: session type (i.e. pre-quit, quit-day, post-quit); session duration; Stop Smoking Practitioner; and the specific BCT;
4. To assess the extent of use of BCTs not included in the particular treatment manual in operation.

5.2. Methods

Ethical Approval

This study received ethical approval by the Clinical, Educational, and Health Psychology Departmental Research Ethics Committee (UCL) [Reference: CEHP/2011/038].

Design

This observational study assessed fidelity of delivery by comparing the content, in terms of component BCTs, of service treatment manuals with the content of transcripts of audio-recorded behavioural support sessions.

Study Sample and Materials

Data were obtained from two English NHS Stop Smoking Services, which typically offer medication and four weekly individual or group behavioural support sessions delivered by a trained, dedicated Stop Smoking Practitioner. The first session is typically a ‘pre-quit’ session, during which the aim is to enhance a smoker’s motivation and self-efficacy to make a quit attempt through activities such as setting clear goals, discussing medication options, general action planning and preparation for quitting. The second session is the ‘quit-day’ session, which focuses on general strategies to avoid smoking cues and overcoming barriers to cessation, as well as maintaining motivation and self-efficacy. The final two sessions are post-quit sessions, which concentrate on providing feedback on progress with the quit attempt, equipping the client with strategies for avoiding smoking in the long term by facilitating relapse prevention and coping, ensuring appropriate use of medications, and promoting an ex-smoker identity.

The first service (i.e. Service 1) is based in the north of England and, at the time of data collection, had the highest CO-validated four-week quit rate of 59% (April to December 2011).

Service 2 is based in North East London, UK, and had an average CO-validated four-week quit rate of 38% (April to December 2011). The average CO-validated quit rate in the NHS Stop Smoking Services in April to December 2011 was 35% (range: 5% to 59%) (NHS Information Centre, 2011).

From each service, two sets of data were collected. First, the treatment manual from each service was obtained. A treatment manual was defined as any guidance document providing a ‘formal, written plan specifying the procedures to be followed in providing a specific treatment or support for smoking cessation to smokers’ (Lorenatto et al. 2012). Manuals are usually written in-house by each service and typically outline the specific format and content of support to be delivered by practitioners in either a pre-quit, quit-day, or post-quit behavioural support session. Manuals therefore represent ‘recommended’ or ‘intended practice,’ and in principle should incorporate national guidance and training standards (Croghan, 2011; West, Lorenatto, et al., 2010; West et al., 2000).

Secondly, audio-recordings of individual behavioural support sessions consecutively delivered to consenting clients as part of routine clinical practice were obtained during a two-month data collection period. This minimized the opportunity for practitioners to select which clients to record. Informed consent to audio-record sessions and have session content examined by research psychologists was obtained from both the practitioner and client prior to audio-recording the session. Sessions were audio-recorded by the practitioner using a discrete audio-recording device. In total, 30 audio-recordings were obtained from Service 1, and 13 from Service 2. Nine audio-recordings from Service 1 were excluded from analysis as they were incomplete; therefore the final sample comprised 21 audio-recordings from Service 1, and 13 from Service 2 (i.e. 34 in total). Of the 21 usable recordings from Service 1, four were of pre-quit

sessions, two quit-day, and fifteen post-quit. From service 2, four recordings were of pre-quit sessions, two quit-day, and seven post-quit. All audio-recordings were anonymised and transcribed verbatim.

Procedure

Coding was conducted by two health psychologists with previous training and experience in using the taxonomy of smoking cessation BCTs to specify components of behavioural support interventions. Both coders independently coded all study materials (i.e. 2 treatment manuals, 34 transcripts) using the taxonomy as a coding framework. The treatment manuals were coded into component BCTs using an established taxonomy of 43 smoking cessation BCTs with demonstrated reliability for coding service treatment manuals (Lorenцatto et al., 2012; Michie, Churchill, et al., 2011; West et al., 2011; West, Walia, et al., 2010). Content of treatment manuals was coded according to session type, that is, content outlining treatment recommendations for either pre-quit, quit-day, or post-quit sessions. Transcripts of audio-recorded behavioural support sessions were coded into component BCTs using a recently adapted taxonomy of 44 smoking cessation BCTs with demonstrated reliability for coding transcripts of audio-recorded behavioural support sessions delivered by NHS Stop Smoking Services (Lorenцatto, West, Seymour, et al., 2013). This adapted taxonomy is an updated version of the original taxonomy of 43 BCTs (Michie, Hyder, et al., 2011). Adaptations included merging typically co-occurring BCTs and refining existing BCT labels and definitions, which resulted in a taxonomy of 40 BCTs (Lorenцatto, West, Seymour, et al., 2013). Since the publication of the original and adapted taxonomies, four additional BCTs have been identified and added to both the original and adapted taxonomy, these are: ‘distract from motivation to engage in the behaviour,’ ‘prompt self-reward,’ ‘prompt behavioural substitution,’ ‘create or

reinforce negative associations' The resulting content of both taxonomies is therefore largely comparable and comprises the same BCTs.

If coders identified the same BCT within a section of text, agreement was registered. Where one coder identified a BCT and the other did not, or a different BCT was identified, disagreement was registered. If an intervention component could not be coded by a BCT label from the taxonomy, this was identified as a potential new BCT. Discrepancies were resolved through discussion or consultation with a behaviour change expert.

Analyses

Inter-rater coding reliability was assessed by examining the proportion of all BCTs identified within a transcript that were identified by both coders (i.e. % positive agreement). Percentage agreement was deemed a more suitable measure of inter-rater reliability for this analysis than Cohen's Kappa for the same reasons outlined in Chapter 4; the items being coded (i.e. sentences in transcripts) are not mutually exclusive as they may contain multiple BCTs within a single item, and BCTs may occur multiple times within a transcript with variable agreement amongst coders, thus precluding a global present/absent rating that is necessary for calculating Kappa (Cohen, 1968; Steijnans, Diletti, Bomches, Greis, & Solleder, 1997).

Extent of fidelity was quantified by calculating what number of BCTs specified in service treatment manuals were also identified in transcripts, and therefore delivered in practice. This was done according to session type rather than overall, as both services' treatment manuals had individual sections outlining treatment specifications for either pre-quit, quit-day or post-quit behavioural support sessions, and the BCTs identified within manuals did not feature uniformly across all three sections of each manual. For example, fidelity of delivery for pre-quit

behavioural support sessions was assessed by examining how many of the BCTs identified in the pre-quit section of the manual were also identified in pre-quit session transcripts (i.e. % delivery of manual-specified content). This was repeated for quit-day and post-quit sessions, and levels of fidelity compared across session types. These analyses were done separately and combined across services. The association between session duration and the proportion of manual-specified BCTs delivered with fidelity was examined by means of Pearson correlations. This analysis was also done separately and combined across services. The mean proportion of manual-specified BCTs delivered by individual practitioners across sessions was calculated for each practitioner and compared across practitioners within each service. Moreover, for each manual-specified BCT, fidelity of delivery was assessed by establishing the proportion of sessions each BCT was delivered in according to manual-specification. This was first done according to session type then combined across session types and services, as not all BCTs featured consistently across all three sections of each manual. Lastly, the proportion of all BCTs delivered within each session that were *not* specified by the manual was also calculated to estimate what proportion of delivered content represented ‘additional’ components.

5.3. Results

1. *Reliability of the fidelity assessment method*

Mean inter-rater reliability for coding was 87.1% agreement across transcripts from both services, which is high [i.e. < 75%, (Popping, 1988)]. Mean agreement for Service 1 was 80.9% (range: 70.9% to 93.7%), and for Service 2, 93.4% (range: 78.4% to 95.6%).

2. *Overall fidelity of delivery in two NHS Stop Smoking Services*

In service 1, across all transcripts, the mean proportion of manual-specified BCTs delivered was 66.4% (SD 16.0; range: 38% to 90%). The average for Service 2 was 65.5% (SD 14.5; range: 35% to 85%) (Appendix 5).

3. *Variation in Fidelity*

i) *according to session type*

The number of BCTs identified in the pre-quit, quit-day, and post-quit sections of each service's treatment manual is provided in Table 10. A full list of BCTs identified within each section of each service's manual is available in Appendix 6. A summary of the mean number of manual-specified BCTs delivered in each session (i.e. % fidelity) is presented according to session type, by service, in Table 10. This, alongside general session characteristics, is available for each of the 34 individual transcripts in Appendix 5.

Across both sets of transcripts, the mean proportion of manual-specified BCTs delivered per session was 66% (SD 14; range: 38% to 83%) for pre-quit sessions; 72% (SD 15.01; range: 50%

to 85%) for quit-day sessions; and 62% (SD 16.4; range: 5% to 90%) for post-quit sessions (Table 10; Appendix 5). In Service 1, fidelity was on average highest for post-quit sessions, with a mean of 69% of manual-specified BCTs delivered per post-quit sessions, and lowest for pre-quit sessions (mean 58%) (Table 10). In Service 2, fidelity was on average highest in quit-day sessions (mean 81%) and lowest in post-quit sessions (56%) (Table 10)

Table 10. Summary of mean session characteristics and the proportion of BCTs specified in the treatment manuals, and BCTs delivered in behavioural support sessions; presented by Stop-Smoking Service and according to session type

Service	Session type (No. of Transcripts)	Mean session duration (Min.Sec) (SD)	Number of BCTs in manual (according to session type)	Mean number of manual specified BCTs delivered (%) (Range)	Mean total number of BCTs delivered (SD)	Mean number of non-manual specified BCTs delivered (% of total) (Range)
Service 1	Pre-Quit (4)	28.59 (SD 5.95)	13 -	7.5 (58%) (R: 38% to 69%)	22 (SD 3.94)	14.5 (66%) (R: 47% to 75%)
Service 1	Quit-day (2)	26.41 (SD 2.72)	8 -	5 (63%) (R: 50% to 75%)	23 (SD 3.94)	18 (78%) (R: 78% to 79%)
Service 1	Post-Quit (15)	11.73 (SD 2.72)	10 -	7 (69%) (R: 40% to 90%)	19 (SD 3.94)	12 (63%) (R: 34% to 82%)
Service 2	Pre-Quit (4)	12.62 (SD 5.26)	12 -	9 (75%) (R:67% to 83%)	23 (SD. 3.55)	14 (61%) (R:44% to 69%)
Service 2	Quit-day (2)	16.66 (SD 4.96)	21 -	17 (81%) (R: 76% to 85%)	29 (SD 2.82)	12 (41%) (R: 41% to 42%)
Service 2	Post-Quit (7)	11.04 (SD 4.33)	17 -	9.6 (56%) (R: 35% to 64%)	20 (SD 3.8)	10.4 (52%) (R:45% to 69%)

ii) *As a function of session duration*

Sessions lasted on average 15.58 minutes (SD 8.4; range: 5.01 to 36.36) and 12.39 minutes (SD 4.7; range: 5.17 to 20.17) for Services 1 and 2 respectively (Table 10; Appendix 5). There was no significant correlation between session duration and the proportion of manual-specified BCTs delivered with fidelity in Service 1 ($r = 0.122$, $p = 0.599$), Service 2 ($r = 0.443$, $p = 0.129$), or across both services ($r = 0.17$, $p = 0.923$).

iii) *According to stop-smoking practitioner*

Behavioural support sessions in Service 1 were delivered by five practitioners, delivering an average of 4.2 sessions each (range: 3 to 6). The mean proportion of manual-specified BCTs delivered by each practitioner was 67% (SD 9.3) across session types, ranging from 55% to 78% (Appendix 5). In Service 2, behavioural support sessions were delivered by four practitioners, each delivering a mean of 3.25 sessions (range: 2 to 4). On average, each practitioner delivered 67.4% (SD 6.5) of manual-specified BCTs across session types, ranging from 58% to 74% (Appendix 5).

iv) *By specific BCT*

Across both services, each manual-specified BCT was delivered according to manual specification in 63% of sessions (SD 28.5, range: 0% to 100%). BCTs for which fidelity of delivery was 100% included: 'boost motivation and self-efficacy,' 'strengthen ex-smoker identity,' 'advise on avoidance of cues for smoking,' and 'information gathering and assessment.' Fidelity was lowest for the BCTs: 'set graded tasks (0%),' 'prompt commitment from the client there and then (15%),' 'facilitate use of social support (15%),' and 'offer/direct towards appropriate written materials (28%)' (Table 11). The proportion of sessions in which

manual-specified BCTs were delivered with fidelity according to session type across both services is available in Appendix 7.

Table 11. Number of behavioural support sessions in which each BCT was delivered according to manual specification across both services

BCT Label	Number of sessions BCT delivered in according to manual (max 34)
1. Provide information on the consequences of smoking and smoking cessation	4/7 (57%)
2. Boost motivation and self-efficacy	2/2 (100%)
3. Provide rewards contingent on successfully stopping smoking	13/22 (59%)
4. Provide rewards contingent on effort or progress	18/22 (82%)
5. Prompt commitment from the client there and then	2/13 (15%)
6. Strengthen ex-smoker identity	2/2 (100%)
7. Identify reasons for wanting and not wanting to stop smoking	9/13 (69%)
8. Measure carbon monoxide (CO) and explain the purpose of CO monitoring	30/34 (88%)
9. Distract from motivation to engage in behaviour	1/2 (50%)
10. Facilitate barrier identification and problem solving	6/9 (67%)
11. Facilitate relapse prevention and coping	7/13 (54%)
12. Facilitate action planning/ develop treatment plan	8/12 (67%)
13. Facilitate goal setting	3/9 (33%)
14. Prompt review of set goals	15/28 (54%)
15. Prompt self-recording	4/6 (67%)
16. Advise on changing routines	2/4 (50%)
17. Advise on environmental restructuring	4/6 (67%)
18. Advise on avoidance of cues for smoking	2/2 (100%)

19. Set graded tasks	0/4 (0%)
20. Advise on stop-smoking medication	32/34 (94%)
21. Advise on/facilitate use of social support	2/13 (15%)
22. Ask about experiences of stop smoking medications that the smoker is using	22/30 (73%)
23. Give options for additional/later support	3/7 (43%)
24. Emphasize choice	2/7 (29%)
25. Build general rapport	22/23 (96%)
26. General practitioner communication approaches	13/13 (100%)
27. Explain expectations regarding treatment programme	9/10 (90%)
28. Offer/direct towards appropriate written materials	7/25 (28%)
29. Information gathering and assessment	12/12 (100%)
30. Provide reassurance	8/13 (62%)

4. *Delivery of BCTs not included in the manual (i.e. additional content)*

In Service 1, sessions contained an average total of 21 BCTs (SD 5; range: 8 to 27), of which 12 (57%; SD 4.8; range: 3 to 21) were *not* manual-specified. In Service 2, sessions contained on average 24 BCTs in total (SD 4.6; range: 12 to 31), of which 12 (50%; SD 3.17; range: 6 to 18) were *not* included in the treatment manual (Table 10; Appendix 5). Across both sets of transcripts (n=34), the BCTs most frequently delivered as ‘additional’ content were: ‘provide feedback on performance (n=34; 100%),’ and ‘provide normative information on others’ experiences (n=30, 88%) (Table 12).

Table 12: Non-manual specified BCTs delivered in behavioural support sessions, presented according to session type and ranked according to frequency of transcripts featured in.

BCT label	Number of transcripts featured in (% of total)
<i>Pre-quit transcripts (max 8)</i>	
‘provide feedback on progress and performance’	8 (100%)
‘provide normative information on other’s experiences’	8 (100%)
‘provide options for additional/later support’	8 (100%)
‘build rapport’	8 (100%)
‘general practitioner communication approaches’	8 (100%)
‘provide reassurance’	8 (100%)
‘explain how nicotine dependence develops’	7 (87.5%)
‘boost motivation and self-efficacy’	6 (75%)
‘emphasise choice’	6 (75%)
‘provide information on the consequences of smoking and smoking cessation’	5 (62.5%)
‘barrier identification and problem solving’	5 (62.5%)
‘reflective listening’	5 (62.5%)
‘goal setting’	4 (50.0%)
‘Advise on conserving mental resources’	4 (50.0%)
‘Ask about current stop smoking medications the smoker is using’	4 (50.0%)
‘strengthen ex-smoker identity’	3 (37.5%)
‘advise on avoidance of cues for smoking’	3 (37.5%)
‘explain expectations regarding the treatment programme’	3 (37.5%)
‘provide rewards contingent on effort or progress’	2 (25.0%)
‘advise on changing routine’	2 (25.0%)

‘tailor interactions appropriately’	2 (25.0%)
‘offer/direct towards appropriate written materials’	2 (25.0%)
‘prompt behavioural substitution’	2 (25.0%)
‘distract from motivation to engage in behaviour’	1 (12.5%)
‘facilitate restructuring of social life’	1 (12.5%)
‘facilitate relapse prevention and coping’	1 (12.5%)

Quit-day transcripts (max 4)

‘provide feedback on progress and performance’	4 (100%)
‘provide normative information on other’s experiences’	4 (100%)
‘emphasise choice’	4 (100%)
‘provide information on the consequences of smoking and smoking cessation’	3 (75%)
‘advise on changing routine’	3 (75%)
‘explain how nicotine dependence develops’	3 (75%)
‘reflective listening’	3 (75%)
‘provide rewards contingent on effort or progress’	2 (50%)
‘goal setting’	2 (50%)
‘prompt review of set goals’	2 (50%)
‘explain expectations regarding the treatment programme’	2 (50%)
‘boost motivation and self-efficacy’	2 (50%)
‘create or reinforce negative associations’	2 (50%)
‘barrier identification and problem solving’	2 (50%)
‘provide options for additional/later support’	2 (50%)
‘build rapport’	2 (50%)
‘general practitioner communication approaches’	2 (50%)
‘provide reassurance’	2 (50%)
‘provide information on withdrawal symptoms’	2 (50%)

‘advise on use of social support’	1 (25%)
‘advise on avoidance of cues for smoking’	1 (25%)
‘advise on conserving mental resources’	1 (25%)
‘advise on environmental restructuring’	1 (25%)
‘prompt self-recording’	1 (25%)
‘action planning/develop treatment plan’	1 (25%)
‘help identify reasons for wanting/not wanting to stop smoking’	1 (25%)
‘strengthen ex-smoker identity’	1 (25%)
‘prompt self-reward’	1 (25%)
‘facilitate restructuring of social life’	1 (25%)
‘emphasise the importance of abrupt cessation’	1 (25%)

Post-quit transcripts (max = 22)

‘provide feedback on progress and performance’	22 (100%)
‘information gathering and assessment’	22 (100%)
‘boost motivation and self-efficacy’	20 (90.1%)
‘provide normative information on other’s experiences’	18 (90.0%)
‘reflective listening’	16 (72.7%)
‘general practitioner communication approaches’	15 (68.1%)
‘provide reassurance’	15 (68.1%)
‘strengthen ex-smoker identity’	14 (63.6%)
‘barrier identification and problem solving’	14 (63.6%)
‘explain how nicotine dependence develops’	13 (59.1%)
‘provide information on withdrawal symptoms’	10 (45.5%)
‘emphasise choice’	9 (40.1%)
‘provide information on the consequences of smoking and smoking cessation’	8 (36.4%)

‘advise on changing routine’	7 (31.8%)
‘build general rapport’	7 (31.8%)
‘advise on conserving mental resources’	6 (27.3%)
‘explain expectations regarding the treatment programme’	6 (27.3%)
‘help identify reasons for wanting/not wanting to stop smoking’	6 (27.3%)
‘create or reinforce negative associations’	6 (27.3%)
‘prompt behavioural substitution’	5 (22.7%)
‘emphasise the importance of abrupt cessation’	4 (18.2%)
‘distract from motivation to engage in behaviour’	4 (18.2%)
‘action planning/develop treatment plan’	4 (18.2%)
‘prompt self-reward’	4 (18.2%)
‘ask about stop smoking medications the client is currently using’	4 (18.2%)
‘advise on avoidance of smoking cues’	2 (9.09%)
‘facilitate restructuring of social life’	2 (9.09%)
‘prompt commitment from the client there and then’	2 (9.09%)
‘advise on use of social support’	2 (9.09%)
‘advise on environmental restructuring’	1 (4.55%)
‘prompt self-recording’	1 (4.55%)
‘goal setting’	1 (4.55%)
‘offer/direct towards appropriate written materials’	1 (4.55%)
‘tailor interactions appropriately’	1 (4.55%)
‘advise on weight control’	1 (4.55%)
‘set graded tasks’	1 (4.55%)

5.4. Discussion

Behaviour change techniques specified in service treatment manuals and delivered in practice could be reliably coded using a taxonomy of smoking cessation of BCTs. This has enabled the comparison of ‘intended’ practice, as specified in treatment manuals, and observed ‘actual’ practice, that is, the assessment of fidelity of delivery in routine clinical practice. Behavioural support delivered by two English NHS Stop Smoking Services contained on average 66% of the BCTs specified in service treatment manuals, indicating that a third of the recommended service content was not typically delivered. Current recommendations for interpreting fidelity data suggest that 80 to 100% delivery of manual-specified content represents ‘high’ fidelity of delivery, whereas < 50% delivery represents ‘low’ fidelity (Borrelli, 2011; Holcombe, Wolery, & Synder, 1994; Noell, Gresham, & Gansle, 2002). While 32% of sessions from both services demonstrated levels of fidelity classifiable as ‘high,’ the remaining two-thirds had levels of fidelity classifiable as ‘moderate’ (~65%) or ‘low.’ These observed levels of fidelity reflect those obtained in similar studies evaluating fidelity of delivery for behaviour change interventions in other domains (Dane & Schneider, 1998; Hardeman et al., 2008; Tober et al., 2008). The present study findings therefore add to a growing body of evidence illustrating the inconsistency with which complex behaviour change interventions are implemented.

There was substantial variability in the extent of fidelity of delivery across sessions from both services. First, variation in fidelity was observed within and across both services according to session type. For example, post-quit sessions displayed the highest levels of fidelity in Service 1, but the lowest in Service 2. Secondly, average levels of fidelity for individual practitioners varied by 23%. This observation may be influenced by professional factors, such as professional background, years of experience, and levels of supervision and training received- all of which

have been shown to vary substantially across practitioners currently employed by the NHS Stop Smoking Services (McDermott, Beard, Brose, West, & McEwen, 2013; McDermott, Thomson, West, Kenyon, & McEwen, 2012; McDermott, West, Brose, & McEwen, 2012). It has not yet been established whether more experienced intervention providers have higher fidelity of delivery, but factors known to influence fidelity are provider's perceived acceptability and effectiveness of treatment (Borrelli, 2011; Borrelli et al., 2005). Furthermore, levels of fidelity of delivery for individual BCTs also varied substantially, from perfect fidelity (100%) to none (0%).

Session duration was not significantly associated with extent of fidelity. In theory, having more time to deliver a behavioural support session would potentially allow for the delivery of a greater volume of content (i.e. more manual-specified BCTs). Given the lack of an observed association between session duration and fidelity, insufficient time to deliver manual-specified content is unlikely to be the explanation. However, time taken to deliver each BCT was not accounted for in analyses. It is possible that some complex BCTs, such as 'barrier identification and problem solving,' take longer to deliver than BCTs such as 'provide reassurance.' This variation across BCTs may have in part mediated the relationship between overall observed fidelity and session duration.

The observed variability in fidelity allows for the identification of problematic areas of intervention implementation and service provision. Identifying those specific practitioners, types of sessions, and individual BCTs for which fidelity is lowest allows for specific training needs to be targeted in future training and improvement guidelines. This enables more efficient, targeted use of training and development resources, and contributes to improvements in the design and implementation of more effective interventions. For example, some BCTs that were included in

the manual have been shown to be significantly associated with improved four-week CO-validated quit rates in the NHS Stop Smoking Services (West, Walia, et al., 2010), yet were delivered with low fidelity in practice [e.g. ‘advise on changing routines (50%),’ and ‘advise on use of social support (15%)’]. If component BCTs that are shown to be effective in research trials are to subsequently achieve target quit outcomes in clinical practice, health professionals responsible for delivering interventions must first adopt these BCTs routinely in practice (Eccles et al., 2009).

The variation in the content of behavioural support delivered is a potential factor explaining the heterogeneity in quit outcomes across and within English NHS Stop Smoking Services. On average, half of all delivered content in both services was not manual-specified. It is unknown whether delivery of these additional BCTs adds to the effectiveness, or dilutes the impact, of the manual-specified BCTs delivered. However, it is certainly clear that this additional, non-manual-specified content increases the variance in the content of interventions delivered, and reduces consistency in the content of support provided across sessions. Attempts to establish associations between the content of behavioural support specified in treatment manuals and quit outcomes cannot be accurately achieved unless the additional content delivered is first identified and accounted for in analyses. A review of audit and feedback interventions found ‘additional’ BCTs present in 86% of studies examined, which hampers the process of synthesizing and evaluating evidence (Gardner, Whittington, McAteer, Eccles, & Michie, 2010).

Furthermore, in the present study, some additionally delivered BCTs featured consistently in all delivered sessions (e.g. ‘provide feedback on performance’), including BCTs such as ‘boost motivation and self-efficacy,’ which have been shown to be effective (West, Walia, et al., 2010). It is possible that practitioners recognize the effectiveness and value of these BCTs, or simply,

that they are easier to deliver routinely or intuitively. If research evidence suggests such BCTs contribute to treatment success, they should be considered for inclusion in treatment manuals.

Findings from this study raise the issue of the extent to which treatment manuals are potentially ‘fit for purpose.’ The evidence-base for BCTs included in the services’ treatment manuals was not assessed, nor was the extent to which manuals are clearly written and conform to training standards or national guidelines. This is necessary for interpreting results of fidelity assessments and the translation of clinical guidelines into practice, since both the planned content and the extent to which content is delivered are essential aspects of assessing the likely impact of a service. For instance, the post-quit sessions delivered in Service 2 had on average lower percentage fidelity (56%) than those delivered in service 1 (69%). However, the post-quit manual from Service 2 contained more BCTs (17) than that in Service 1 (10). The mean number of BCTs delivered per post-quit session in Service 2 was higher than that from Service 1 (approximately 10 vs. 7 BCTs respectively). Therefore, although the percentage of fidelity appears to be lower in Service 2, the post-quit sessions may in fact have been potentially more effective in helping clients to successfully quit as a higher number of techniques were delivered. This in turn raises the question as to whether achieving 100% fidelity is always necessary to produce desired treatment outcomes. Combining analyses of the extent to which manuals are based on good evidence with an assessment of fidelity will give a more comprehensive assessment of delivery, and stronger evidence of intervention effectiveness, compared with considering either evidence or fidelity in isolation.

The question of whether 100% fidelity of intervention delivery is a desirable aim has also been subject to wider, recent debate (Borrelli, 2011). Strict adherence to treatment manuals may be detrimental to therapeutic interaction, as not all content specified in manuals will be relevant to all of the individual needs and concerns of each intervention recipient (Kendall, Gosch, Furr, & Sood, 2008; Leventhal & Friedman, 2004). The delivery of additional, non-manual specified BCTs may be one means by which practitioners are tailoring the content of support provided to client needs and are thus increasing flexibility in their practice. Furthermore, the manuals from both services contained a high number of BCTs, which may not always be feasible or appropriate to deliver in practice. However, manuals are essential to maintaining a degree of consistency and standards in service provision. Some argue in favour of a middle ground in which core, prescribed intervention components are delivered with strict fidelity, alongside a permissible degree of additional flexibility and tailoring in how non-essential components are delivered (Borrelli, 2011; Collins et al., 2009; Kendall et al., 2008). Such an approach does not compromise fundamental treatment integrity, and offers a potentially more feasible, realistic and beneficial model of treatment delivery.

Limitations to the current study first include the sample size of only two services. This sample served as a pilot on which to test the feasibility of the taxonomy as a fidelity assessment tool. These findings may not reflect all sessions delivered by practitioners within that service, other services, or behavioural support interventions delivered in contexts other than the English NHS Stop Smoking Services. In addition to assessing fidelity in terms of presence or absence of BCTs, it would be a step forward to establish a method for comprehensively examining the other four dimensions of Borelli's model (i.e. design, training, receipt, enactment) (Borrelli, 2011), as well as the quality with which BCTs are delivered.

An aspect of the methodology that could be perceived as a limitation is the use of audio-recording rather than video-recording to measure ‘actual’ practice delivered. Audio-recording was selected as it interferes less with practice, and is more feasible, and economic to obtain. All BCTs in the taxonomy require some degree of verbalization as part of their operationalization (i.e. ‘advise on,’ ‘offer’); video recording is therefore unlikely to have substantially offered additional information in terms of content delivered. Furthermore, practitioners were aware of their sessions being recorded and subsequently analysed, which may have prompted attempts to improve their practice as a result of social desirability or demand characteristics. Therefore, these sessions may not be representative of typical practice; however, these sessions are likely to represent a ‘best case scenario,’ and over-estimate rather than under-estimate fidelity of delivery.

An additional key question is whether fidelity is associated with improved quit outcomes. Interventions implemented with higher levels of treatment fidelity have been shown to be associated with better outcomes in domains such as psycho-educational, preventative school-based interventions with adolescents (Durlak & DuPre, 2008). In the present study Services 1 and 2 had high and average success rates respectively, yet had similar observed levels of fidelity delivery; the extent to which differences in fidelity may help explain the variance in quit rates could be examined in future research with a representative sample.

This study illustrates the reliability of the taxonomy as a method for assessing fidelity and monitoring the implementation of behavioural support interventions for smoking cessation. The taxonomy provides a consistent, common language through which to identify, characterize, and compare the component BCTs comprising the content of treatment manuals and session transcripts. This comparison enables the quantification of the extent of, and variations in, the fidelity of delivery of behavioural support in clinical practice. The taxonomy therefore represents

a feasible, systematic method by which fidelity of complex behaviour change interventions may be assessed. Current implementation of behavioural support interventions as observed in a limited number of sessions from a small sample of the NHS Stop Smoking Services appears to be inconsistent and poorly adherent to manual specifications. The generalizability of these findings to a larger, more representative number of sessions needs to be examined, as well as the extent to which these findings may apply to behavioural support delivered in other contexts or modes of delivery, such as telephone-based support.

5.5. Citation for the published peer-reviewed journal article of this study:

Lorencatto, F., West, R., Christopherson, C., & Michie, S. (2013). Assessing fidelity of delivery of smoking cessation behavioural support in practice. *Implementation Science*, 8, 40. doi: 10.1186/1748-5908-8-40.

For published-peer reviewed article see Appendix 11.

CHAPTER 6: Fidelity of delivery of telephone-based behavioural support

6.1. Introduction

A large number of current adult smokers (~70%) are interested in quitting smoking (Orleans, 2007). Smokers can choose from a range of interventions to support them during their quit attempt, including stop smoking medications (e.g. varenicline, bupropion, and several forms of nicotine replacement therapy) and behavioural support. Behavioural support interventions have been delivered through several modes of delivery, including very brief advice from physicians (Stead et al., 2013), more intensive support via individual and group face-to-face sessions with a trained advisor (Lancaster & Stead, 2005a; Stead & Lancaster, 2005), self-help materials (Lancaster & Stead, 2005b), telephone (Stead, Perera, & Lancaster, 2006), text messaging (Free et al., 2011; Rodgers et al., 2005), web-based interventions (J. Brown et al., 2012; Shahab & McEwen, 2009), and smart-phone applications (Abroms, Padmanabhan, Thaweethai, & Phillips, 2011). Although there is evidence from evaluative trials for the effectiveness of behavioural support interventions delivered through all of these modalities, a consistent finding across all of these modes of delivery is that the outcomes of behavioural support interventions are extremely heterogeneous (Lancaster & Stead, 2005a, 2005b; Shahab & McEwen, 2009; Stead et al., 2013; Stead & Lancaster, 2005; Stead et al., 2006). Where these interventions have been implemented in clinical practice, such as in the English NHS Stop Smoking Services, quit rates within, as well as across, individual services have also been shown to vary substantially (NHS Information Centre 2011).

In the context of clinical practice, a number of service level factors may contribute to this variation in quit outcomes, one of which is the content of behavioural support interventions delivered by different services and practitioners. To date, attempts to examine variability in the content of behavioural support interventions delivered in practice have relied on service

treatment manuals as a proxy indicator of what is expected or intended to be delivered in practice by a Stop Smoking Service's practitioners (Lorenatto, West, & Michie, 2012; Michie, Churchill, & West, 2011; West, Evans, & Michie, 2011; West, Walia, Hyder, Shahab, & Michie, 2010). However, given evidence that fidelity to treatment manuals is typically poor for complex behaviour change interventions, there is a need to objectively verify practice (Borrelli, 2011). Until recently, we lacked methods for systematically specifying and examining the specific components comprising the content of smoking cessation behavioural support delivered in clinical practice. In Chapter Four of this thesis, it was demonstrated that the taxonomy may be reliably applied to achieve this (Lorenatto, West, Seymour, & Michie, 2013). This enabled the assessment of intervention fidelity reported in Chapter Five, which involved examining the extent to which the content (i.e. component BCTs) specified in treatment manuals was consistently delivered as part of behavioural support interventions delivered by the NHS Stop Smoking Services. Delivered practice was objectively verified via transcripts of audio-recorded behavioural support sessions. Behavioural support was found to be neither consistent with, nor fully adherent to, specifications in treatment manuals and varied substantially according to session types, individual practitioners and component BCTs (Lorenatto, West, Christopherson, & Michie, 2013). Such variability in the content of behavioural support interventions delivered in clinical practice may explain in part the observed variability in quit outcomes across NHS Stop Smoking Services.

These findings were from a pilot study aiming to establish the reliability of the taxonomy as a fidelity assessment tool, and were based on a limited number of audio-recordings of behavioural support sessions from only two services and of behavioural support interventions delivered in a single mode (i.e. individual, face-to-face behavioural support). It is therefore not possible to

generalise from these data. The extent to which these findings may be generalised to a larger, more representative sample of sessions from a service, as well as to behavioural support delivered in different modes, remains to be ascertained.

Telephone-delivered smoking cessation behavioural support has become increasingly prevalent in recent years (Zhu et al., 2002). Telephone-support interventions can be either proactive or reactive (Lichtenstein, Glasgow, Lando, Ossip-Klein, & Boles, 1996). Proactive telephone support involves counsellors initiating telephone contact with smokers to provide support during the quit attempt. Reactive telephone support involves smokers directly initiating engagement with the service, such as by contacting a quit-line (Lichtenstein et al., 1996). Telephone support has been used as a primary intervention, and as a supplement to face-to-face support sessions and/or pharmacotherapy (i.e. follow up calls scheduled in between sessions) (Lichtenstein et al., 1996). Telephone support offers several advantages over intensive face-to-face interventions, including increased accessibility and the potential to reach a wider number of smokers or underserved populations, such as smokers with mobility difficulties or those residing in geographically remote locations. Telephone support also offers increased privacy, anonymity, scheduling flexibility and convenience (Zhu et al., 1996). Furthermore, telephone support services are likely to be cost-effective given their moderate operation costs, potential for increased reach (Lichtenstein et al., 1996) and evidence of effectiveness (Stead et al., 2006; Zhu et al., 2002).

National quit-lines have been established in the UK, Australia and the USA (Stead et al., 2006; Zhu et al., 2002). As with other types of behavioural support, the outcomes of telephone-delivered behavioural support interventions vary substantially in both practice (NHS Information Centre, 2011) and research settings (Stead et al., 2006). This variability remains despite the widespread use of treatment manuals in the delivery of telephone-based behavioural support

interventions to promote consistency in the format and content of support delivered within services (Wilson, 1996). Trials of telephone-delivered smoking cessation behavioural support interventions have trained counsellors to deliver support according to detailed, structured, and often semi-scripted counselling treatment manuals (An et al., 2006; Curry, McBride, Grothaus, Louie, & Wagner, 1995; Zhu et al., 1996). Similarly, most NHS Stop Smoking Services, including quit-lines, have in-house treatment manuals providing standardised guidance for practitioners regarding the specific content to be delivered during sessions (West, Walia, et al., 2010).

Therefore, telephone-based interventions provide a good opportunity to investigate the extent to which findings of poor fidelity to treatment manuals may generalise across modes of delivery and contexts. Fidelity may be better in telephone support as it may be easier for quit-line practitioners to complete assessment forms and discretely refer to a treatment manual throughout the session without disrupting the clinical interaction. This study aimed to extend the method for assessing fidelity of delivery of smoking cessation behavioural support interventions reported in Chapter Five to telephone-delivered support, using a larger, more representative, sample of audio-recordings from a UK national quit-line service. This study used the same methods and analyses as those involved in assessing fidelity of individual, face-to-face behavioural support reported in Chapter Five (Lorenatto, West, Christopherson, et al., 2013). This study also investigated discrepancies between practitioners self-reported and actual practice, that is, what practitioners '*say they do,*' vs. '*actually do.*' This is important to examine given the well-established differences in the wider healthcare literature between healthcare professionals' reported practice and observed practice (Cabana et al., 1999; Jones, Gerrity, & Earp, 1990). The extent to which this discrepancy is applicable to Stop Smoking Practitioners is unknown.

6.1.1. Aims and Objectives

The specific objectives of this study are to:

1. Assess the reliability of an established fidelity assessment method when applied to telephone-based smoking cessation behavioural support
2. Monitor implementation of telephone-delivered behavioural support by assessing the fidelity of delivery of behavioural support in a UK national smoking cessation quitline
3. Investigate variation in fidelity according to: i) session type, ii) practitioner, iii) session duration, and iv) specific BCTs
4. Examine the extent of use of additional BCTs not included in the service treatment manual.
5. Examine discrepancies between self-reported and actual delivery of BCTs.

6.2. Methods

Ethical Approval

This study received ethical approval by the Clinical, Educational, and Health Psychology Research Department Ethics Committee (UCL) [Reference: CEHP/2011/038].

Design

This cross-sectional study objectively verified fidelity of delivery by comparing the content, in terms of component BCTs, of treatment manuals to that of transcripts of audio-recorded, telephoned-delivered behavioural support sessions.

Study sample and materials

Data were obtained from a national UK quit-line service, which employs four trained Stop Smoking Practitioners who provide dedicated telephone-based smoking cessation behavioural support. The behavioural support is typically delivered over four sessions, following the same format of sessions delivered in face-to-face sessions: a pre-quit session, quit-day session, and post-quit sessions. The service also offers pharmacological support in the form of nicotine replacement therapy vouchers that are mailed to clients. In 2011, the service had an average self-reported four-week successful quit rate of 51.8%.

Practitioners had on average 13.5 years of experience working as a dedicated Stop Smoking Practitioner (range: 13-15), and three had passed the National Centre for Smoking Cessation and Training's skills and knowledge training for delivery of smoking cessation behavioural support (see: <http://www.ncsct.co.uk>) (Brose, West, Michie, & McEwen, 2013). All practitioners reported that they were aware of the service treatment manual, and that they had been observed in practice and received feedback on performance as part of their training.

From the quit-line, two sets of data were obtained. First, the quit-line service treatment manual, which is based on the UK national treatment guidance and training standards for delivering smoking cessation behavioural support (Croghan, 2011; West, Lorencatto, et al., 2010). The treatment manual clearly outlines the format and content of sessions to be delivered to *all* clients in either a pre-quit, quit-day, or post-quit behavioural support session. This is accompanied by illustrative dialogues demonstrating how to deliver the recommended content.

Secondly, a set of seventy-five behavioural support sessions consecutively delivered to consenting smokers were audio-recorded using a discrete device during a six month data collection period. This minimised the risk of practitioners selecting which sessions to audio-record. Informed consent to audio-record sessions was obtained from practitioners in writing and clients by audio-recorded telephone. Eleven audio-recordings were excluded as they were incomplete, resulting in a final sample of 64 audio-recordings of three different types of sessions reflecting the three different stages of a quit attempt: pre-quit (n=27), quit-day (n=16), and post-quit (n=21). Recordings were anonymised and transcribed verbatim.

Procedure

The procedure and analyses in the present study followed those developed for assessing fidelity of face-to-face individual behavioural support (see Chapter 5) (Lorencatto, West, Christopherson, et al., 2013). Two researchers with previous experience of coding using the established taxonomy of smoking cessation BCTs, independently coded the service treatment manual and session transcripts into component BCTs using the taxonomy of 44 smoking cessation BCTs (Michie, Hyder, Walia, & West, 2011). The taxonomy has demonstrated reliability as a framework for identifying and characterising component BCTs in service treatment manuals (Lorencatto, West, Christopherson, et al., 2013; Lorencatto et al., 2012;

Michie, Churchill, et al., 2011; West et al., 2011; West, Walia, et al., 2010), as well as transcripts of audio-recorded sessions (Lorenatto, West, Christopherson, et al., 2013; Lorenatto, West, Seymour, et al., 2013). Data were extracted on the number of BCTs identified within each section of the manual (pre-quit, quit-day or post-quit), as well as within each transcript.

If coders identified the same BCT within a section of text, agreement was registered. Where one coder identified a BCT and the other did not, or a different BCT was identified, disagreement was registered. If an intervention component could not be coded by a BCT label from the taxonomy, this was identified as a potential new BCT. Discrepancies were resolved through discussion or consultation with a behaviour change expert.

All practitioners were asked to complete the NCSCT's annual practitioner's survey, from which the demographic and professional characteristics of the practitioners were drawn (McDermott, Thomson, West, Kenyon, & McEwen, 2012). The survey also assessed practitioner's self-reported use of 16 BCTs that have been shown to be significantly associated with improved four-week quit outcomes, and therefore represent those BCTs with the currently best established evidence base (see Table 15) (West, Walia, et al., 2010). Self-reported use of evidence-based BCTs was assessed for each BCT with the five-point item: 'Thinking about all of the sessions you have delivered over the last 3 months, with what proportion of your clients do you think that you performed the following activities?' (0- 'none of them' to 4- 'all of them').

Analyses

A sub-sample of 25% of transcripts was double-coded to assess inter-rater reliability. Percentage agreement was used to assess reliability rather than Cohen's Kappa. Given the high number of BCTs in the taxonomy (i.e. 44), the probability of chance selecting a particular code is low, and

as Kappa corrects for chance agreement amongst multiple coders, use of Kappa is likely to underestimate reliability (Steinijans, Diletti, Bomches, Greis, & Solleder, 1997). Moreover, the items being coded (i.e. sentences in transcripts) are not mutually exclusive, and multiple BCTs may occur within a single item and at multiple points within the transcript with coders potentially agreeing on one instance of identification of a particular technique but not the other; thus precluding a global present/absent rating that is required to calculate Kappa.

Fidelity was quantified by assessing the proportion of BCTs specified in the service treatment manual that were delivered in practice. This was first done according to session type rather than overall as the service treatment manual had individual sections pertaining to the three different stages of the quit attempt and BCTs did not feature uniformly across these three sections of the manual. For example, fidelity of delivery for pre-quit sessions was established by examining the proportion of BCTs specified in the pre-quit section of the manual that was delivered in each pre-quit behavioural support session. This was in turn repeated for quit-day and post-quit sessions, then compared across sessions to examine variability in fidelity. To obtain an overall estimate of fidelity, the percentage of manual-specified BCTs delivered across the three types of sessions was averaged.

Variation in extent of fidelity was also examined according to numerous factors. First, variation in fidelity according to individual practitioner was examined by comparing the average proportion of manual-specified BCTs delivered by each practitioner within their sessions. Secondly, the association between session duration and variation in the proportion of manual-specified BCTs delivered was examined using Pearson Correlation. Subsequently, to assess variation in fidelity across BCTs, the proportion of sessions in which each BCT was delivered according to manual specification was calculated. This was first done according to session type,

and then averaged across session types as not all BCTs featured consistently across all three sections of the manual. Lastly, to ascertain what proportion of delivered session content was not manual-specified (i.e. ‘additional content’), the number of BCTs delivered that were *not* included in the manual was calculated as a percentage of the total number of BCTs delivered within a session.

To establish a percentage of self-reported use of evidence-based BCTs across practitioners, the total scores for self-reported use of each of the 16 evidence-based BCTs was established by summing response ratings for each BCT across the four counsellors. For each BCT, this total score was presented as a percentage of the maximum possible total score of 16. The resulting percentages represent the percentage of sessions that practitioners report using each of the evidence-based BCTs in. The percentage of *actual* use for each evidence-based BCT was assessed by calculating the total number of sessions across practitioners that each BCT was actually delivered in. This was then presented as a percentage out of the maximum possible 64 sessions. Differences between percentage self-reported and percentage actual use were examined for each evidence-based BCT using a paired-samples t-test.

6.3. Results

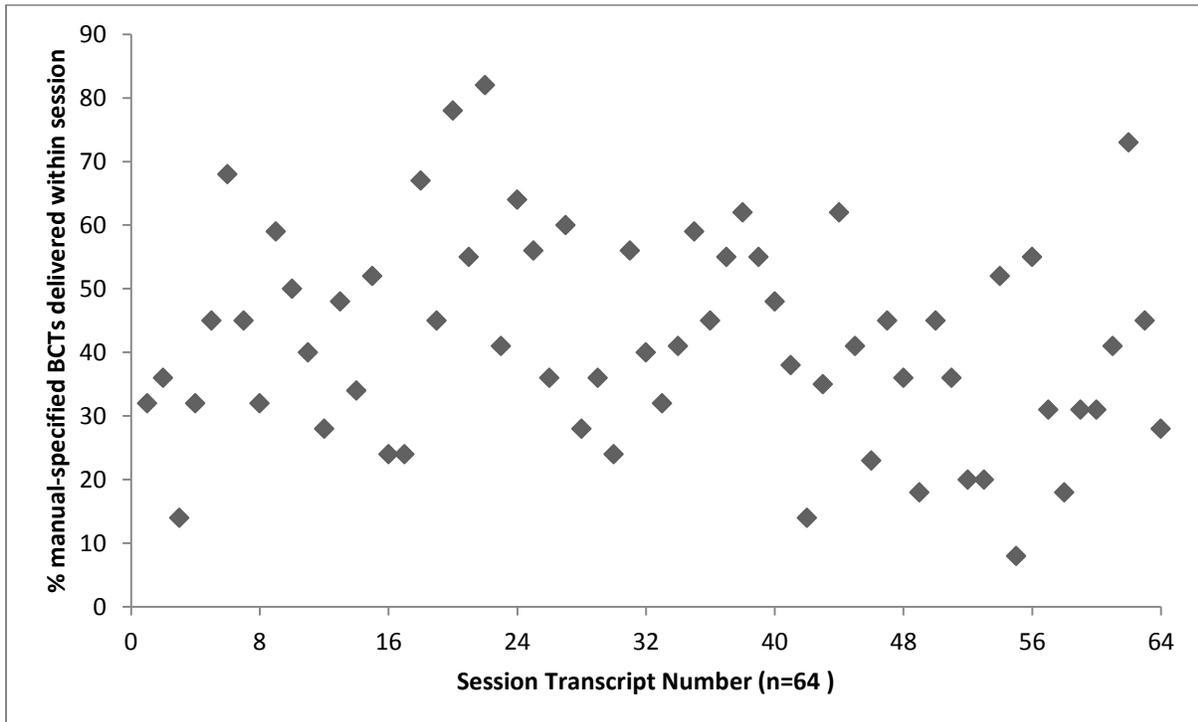
1. Reliability of fidelity assessment method

Average inter-rater reliability for coding was 81.9% across transcripts (range: 75.4% to 89.9%), which is high (i.e. >75%) (Popping, 1988). Discrepancies were easily resolved through discussion and no new additional BCTs identified.

2. Fidelity of delivery (overall)

Across transcripts of all session types, on average, 41.8% (range: 8-82%) of manual-specified content was delivered in practice (Table 13; Figure 10).

Figure 10. Percentage of manual-specified BCTs delivered (i.e. % fidelity) in each examined session (n=64)



3. *Variation in fidelity*

i) *According to session type*

The pre-quit section of the manual contained 22 BCTs (Appendix 8), of which on average 10 (46%) were delivered (SD 16.9; range: 14-82%) (Table 13). The manual content relating to quit-day support contained 25 BCTs of which on average 9 (35%) were delivered (SD 14.8; range: 8-60%). The post-quit support section of the manual featured 28 BCTs, of which on average 12 (42%) were delivered (SD 16.3; range: 8-82%) (Table 13).

Table 13. Session characteristics and the proportion of BCTs specified in the treatment manuals delivered in behavioural support sessions; summarised across practitioner and session type.

Practitioner ID	Session type (1=pre-quit; 2= Quit day; 3=Post-quit) (N sessions)	Duration (sec) (range)	No. of BCTs in Manual (according to session type)	Average No. of manual-specified BCTs delivered (%; range)	Average Total No. of BCTs in session (range)	Average No. of non-manual specified BCTs in session (%; range)
P01	1 (n=10)	1490 (414-3754)	22	9 (41%) (14-68%)	13 (4-23)	4 (31%) (17-53%)
P01	2 (n=2)	1481 (742-2221)	25	8 (32%) (28-40%)	15 (13-16)	6 (40%) (40-40%)
P01	3 (n=5)	716 (248-1105)	28	10 (36%) (24-52%)	11 (7-16)	0 (0%) (0-1)
P02	1 (n=7)	1653 (797-2375)	22	13 (59%) (41-82%)	17 (10-24)	4 (24%) (10-33%)
P02	2 (n=9)	931 (475-1607)	25	10 (40%) (24-60%)	17 (9-25)	7 (41%) (33-53%)
P02	3 (n=11)	947 (317-1521)	28	14 (50%) (14-62%)	16 (6-21)	2 (13%) (6-33%)
P03	1 (n=7)	877 (627-1357)	22	8 (36%) (18-45%)	9 (4-13)	1 (11%) (0-31%)
P03	2 (n=4)	324 (172-864)	25	6 (24%) (8-52%)	9 (3-20)	3 (33%) (17-38%)
P03	3 (n=5)	391 (154-594)	28	9 (32%) (18-55%)	14 (5-18)	2 (14%) (0-31%)
P04	1 (n=3)	1870 (1160-2531)	22	12 (54%) (41-73%)	16 (13-22)	5 (31%) (23-36%)
P04	2 (n=1)	288	25	7 (28%)	13	6 (46%)
P04	3 (n=0)	-	-	-	-	-

ii) *According to individual practitioner*

Of the 64 sessions examined, the four practitioners delivered on average 16 sessions each (range: 4-27). The average proportion of manual-specified BCTs delivered by each practitioner was 41.8%, ranging from 32% to 49% across practitioners (Table 13).

iii) *As a function of session duration*

On average, sessions lasted 12.40 minutes (SD 6.55). There was a positive correlation between the duration of a session and the proportion of manual-specified BCTs delivered in the session ($r=0.452$, $p<.01$) (Table 13).

iv) *By specific BCT*

Each manual-specified BCT was delivered in 40% of the appropriate sessions (range: 0 to 95%) (Appendix 9). BCTs for which fidelity was highest were: ‘giving options for additional and/or later support (delivered appropriately in 95% of sessions),’ ‘information gathering and assessment (88%),’ and ‘providing feedback on current behaviour and progress (85%).’ BCTs for which fidelity was lowest were: ‘set graded tasks (0%),’ ‘Measure CO and explain the purposes of CO monitoring (2%),’ and ‘prompt commitment from the client there and then (3%)’ (Table 14).

Table 14. Number of behavioural support sessions each BCT was delivered in according to manual specification across session types.

BCT	Total No. sessions BCT delivered in according to manual specification
Set graded tasks	0 /16 (0%)
Prompt commitment from the client there and then	2/64 (3%)
Measure CO and explain the purposes of CO monitoring	1/64 (2%)
Explain the importance of abrupt cessation	4/64 (6%)
Provide reassurance	41/64 (64%)
Advise on avoiding social cues for smoking	5/64 (8%)
Prompt self-recording	2/21 (10%)
Advise on environmental restructuring	5/43 (12%)
Promote self-reward	2/16 (13%)
Advise on/facilitate use of social support	8/64 (13%)
Advise on conserving mental resources	3/21 (14%)
Facilitate action planning/ develop a treatment plan	7/48 (15%)
Advise on changing routine	3/16 (19%)
Facilitate relapse prevention and coping	8/37 (22%)
Distract from motivation to engage in behaviour	4/16 (25%)
Strengthen ex-smoker identity	17/64 (27%)
Emphasise choice	9/27 (33%)
Provide information on the health consequences of smoking and smoking cessation	17/48 (35%)
Facilitate barrier identification and problem solving	27/64 (42%)
Provide rewards contingent on not smoking	9/21 (43%)
Facilitate identification of reasons for wanting and not wanting to stop smoking	9/21 (43%)
Prompt review of set goals	9/21 (43%)
Ask about experiences of stop smoking medication that the smoker is currently using	17/37 (46%)
Build general rapport	39/64 (61%)
Provide normative information about others' behaviour and experiences	41/64 (64%)
Boost motivation and self-efficacy	42/64 (66%)
Provide rewards contingent on effort or progress	14/21 (67%)
Advise on stop smoking medication	49/64 (75%)
Facilitate goal setting	22/27 (81%)
General communication approaches	52/64 (81%)
Provide feedback on current behaviour and progress	18/21 (86%)

Give options for additional and later support	61/64 (95%)
Information gathering and assessment	57/64 (88%)
Explain how tobacco dependence develops	7/43 (16%)
Explain expectations regarding the treatment programme	28/43 (65%)
Provide information on withdrawal symptoms	11/64 (17%)
reflective listening	13/21 (62%)

4. *Deliver of BCTs not included in the manual (i.e. additional content)*

Sessions contained on average 15 BCTs per session (SD 5.3) (Table 13). Of these, on average 3 (23%) were not manual-specified (range: 0-53%). A full list of BCTs most frequently delivered as additional content in each session type is available in Appendix 10.

5. *Self-reported vs. Actual use of sixteen evidence-based BCTs*

The average score for self-reported use of each of the 16 evidence-based BCTs was 12 (SD 3.03); indicating that practitioners reported using a BCT on average in 75% of sessions (range: 31-100%). In contrast, the average number of sessions each BCT was actually delivered in was 22, corresponding to 35% actual use of each evidence-based BCT (range: 2-89%). Differences between the average percentage of reported and actual use across each of the 16 evidence-based BCTs were significant [$t=-5.52$ (15), $p<.001$] (Table 15).

Table 15. Percentage self-reported and actual use of sixteen evidence-based BCTs.

BCT Label	Cumulative score of self-reported use across counselors (%) (max=16; 100%)	Number (%) of sessions BCT actually delivered in across counselors (max= 64; 100%)
‘Boost motivation and self-efficacy’	14 (88%)	45 (71%)
‘Provide rewards contingent on not smoking’	16 (100%)	17 (27%)
‘prompt commitment from the client there and then’	12 (75%)	2 (3%)
‘strengthen ex-smoker identity’	11 (69%)	15 (24%)
‘Measure CO’	5 (31%)	1 (2%)
‘Facilitate relapse prevention and coping’	13 (81%)	8 (12%)
‘Advise on changing routine’	14 (88%)	12 (19%)
‘Advise on conserving mental resources’	14 (88%)	8 (13%)
‘Advise on stop smoking medication’	13 (81%)	56 (88%)
‘Advise on/facilitate use of social support’	13 (81%)	10 (15%)
‘Ask about experiences of stop smoking medication that the smoker is currently using’	13 (81%)	27 (37%)
‘Give options for additional and later support’	14 (88%)	57 (89%)
‘General practitioner communication approaches’	11 (69%)	42 (65%)
‘Provide reassurance’	13 (81%)	45 (71%)
‘Provide information on withdrawal symptoms’	11 (69%)	13 (21%)
‘Explain purpose of CO monitoring’	5 (31%)	1 (2%)

6.4. Discussion

In a representative sample of behavioural support sessions delivered by a UK national quit-line service it was found that on average, less than half (42%) of manual-specified content was routinely delivered in practice. This is considered to be ‘low’ fidelity according to current guidelines for interpreting fidelity data (Borrelli, 2011). The content of telephone-delivered behavioural support for smoking cessation can be reliably coded into component BCTs using an established taxonomy (Lorencatto, West, Seymour, et al., 2013; Michie, Hyder, et al., 2011). Inter-rater coding reliability of applying the BCT taxonomy was consistently high (average percentage agreement 81.9%), and achieved levels similar to those obtained when coding the content of face-to-face behavioural support sessions (Lorencatto, West, Christopherson, et al., 2013; Lorencatto, West, Seymour, et al., 2013). The presently found levels of fidelity are lower than those observed for behavioural support delivered in person (66%) (Lorencatto, West, Christopherson, et al., 2013) and are consistent with those found in systematic reviews and trials of behaviour change interventions in other domains, such as physical activity and drug abuse prevention in schools (i.e. 40-50% fidelity) (Dane & Schneider, 1998; Dusenbury, Brannigan, Falco, & Hansen, 2003; Hardeman et al., 2008). The current findings therefore add to the evidence of the fidelity of delivery of behavioural support interventions for smoking cessation and the wider implementation of complex behaviour change interventions in practice.

The majority of fidelity assessments that have been conducted to date have been in the context of an evaluative research trial (Collins et al., 2009; Dane & Schneider, 1998; Dusenbury et al., 2003; Hardeman et al., 2008). The previous study in this thesis provided a pilot example of a fidelity assessment conducted in the context of behavioural support interventions delivered in clinical practice (Lorencatto, West, Christopherson, et al., 2013). The present study extends this

finding to a larger, more representative sample of sessions obtained from a national quit-line service in clinical practice, representing a different behavioural support context, and further illustrates the variability in the implementation and fidelity of delivery of smoking cessation behavioural support interventions. For example, as with face-to-face support, fidelity was shown to vary according to session type, practitioner, and BCT. Fidelity was lowest in pre-quit sessions (35%), for a specific practitioner (35%), and the BCTs ‘set graded tasks (0%)’ and ‘measure and explain the purpose of CO monitoring (2%).’ Such findings have implications for improving practice and designing more effective interventions, as it allows for the identification of specific training needs and targeted use of training and professional development resources.

Although there were similarities between the variation in fidelity of delivery of telephone and face-to-face behavioural support interventions, differences were also observed. For example, in face-to-face behavioural support sessions, no association between session duration and extent of fidelity was observed (Lorenatto, West, Christopherson, et al., 2013). However, in the present analysis of telephone-support, it was found that longer session duration was significantly associated with higher fidelity. This finding is consistent with reviews of fidelity of delivery for complex interventions in other domains (Moncher & Prinz, 1991). The lack of an observed association between duration and fidelity for face-to-face support may reflect the narrower range of session duration for sessions delivered face-to-face rather than via telephone (5-36 minutes vs. 3-62 minutes respectively). Furthermore, telephone-delivered sessions contained less non-manual specified BCTs (i.e. additional content), than face-to-face sessions (23% vs. 65% respectively) (Lorenatto, West, Christopherson, et al., 2013). It remains unclear whether additional content is beneficial or detrimental to the delivery of manual-specified content. It may introduce substantial variability into the content of sessions delivered in practice, or it may enhance the effect of

delivered content through the delivery of additional, adjunctive BCTs that support the delivery manual-specified BCTs.

Stop Smoking Practitioners over-reported the extent to which they deliver BCTs in practice. This findings has implications from a research perspective as it demonstrates that clinician self-reported practice in questionnaires, interviews and assessments cannot be used as a reliable or valid proxy for actual practice when assessing implementation of an intervention. This finding is also consistent with studies demonstrating differences between what physicians say they do, and what they actually do (Cabana et al., 1999; Jones et al., 1990). These findings underline the need to increase observation of healthcare providers in practice, in order to audit and monitor implementation in practice and provide accurate feedback to clinicians in improving their practice.

These findings also raise the issue of the extent to which manuals are fit for purpose. One explanation for the low fidelity in the quit-line service may be that manuals reflect unrealistic expectations of what can be delivered within the limitations of a particular context (e.g. session duration, expertise of practitioners). The treatment manual for the quit-line was extremely comprehensive, expecting practitioners to deliver up to 28 BCTs per session, which on average only lasted approximately 13 minutes; that is equivalent to approximately two BCTs per minute, assuming the practitioner spoke for the whole session, which is unlikely to be the case. Delivering such a high volume of BCTs may not be feasible or relevant to all clients, and may even be detrimental to the therapeutic relationship. For example, it would be inappropriate to insist on delivering a manual-specified BCT, such as facilitating the client's use of social support, if this is not an area of concern or relevance to their personal quit attempt.

Furthermore, it is unclear whether high fidelity will necessarily lead to improved quit-rates. The issues that need to be addressed include the effectiveness of each BCT, their combinations and the optimal ratio of time to BCTs delivered. Some argue in favour of flexibility in delivery rather than strict, 100% required fidelity to treatment manuals (Leventhal & Friedman, 2004). However, the use of treatment manuals, and fidelity to treatment manuals, is important for providing a benchmark for practice and promoting consistency and standards in service provision (Michie, 2008). The issue is the level of detail vs. general principles that are manualised.

The present study demonstrates the application of a reliable fidelity assessment method to monitor the implementation of telephone-delivered behavioural support. Observed findings in a UK National quit-line illustrate the current variable implementation of evidence-based behavioural support interventions in clinical practice and highlight particular areas in which variability in intervention delivery may occur. Whilst the general findings of this study are consistent with previous evidence about the delivery of behavioural interventions and is based on a larger sample of sessions delivered in practice, caution needs to be observed when generalising these results since the data have been drawn from a single quit-line service. This study provides an example of a reliable fidelity assessment method for clinical practice settings and emphasises the need to establish routine procedures for monitoring the fidelity of delivery of smoking cessation behavioural support interventions. Assessing fidelity of delivery is one step towards identifying targets for future interventions to improve implementation, service provision, and ultimately outcome. It is also necessary to examine *how well* interventions are delivered to obtain a more comprehensive insight into current implementation, and also to examine the impact of the extent of implementation on outcomes.

CHAPTER 7: Assessing quality of goal-setting in behavioural support for smoking cessation and associations with quit attempts

7.1. Introduction

The comprehensive assessment of intervention implementation involves examining both *how much* of an intervention is delivered (i.e. quantity), alongside *how well* an intervention is delivered (i.e. quality) (Borrelli, 2011; Durlak, 1998). Chapters Five and Six of this thesis present the results of the application of a recently developed method to monitor the extent to which individual face-to-face and telephone-based smoking cessation behavioural support interventions are delivered in practice with fidelity to manual specifications (i.e. quantity of delivery) (Lorenцatto, West, Christopherson, & Michie, 2013; Lorenцatto, West, Seymour, & Michie, 2013). Fidelity of delivery is a pre-requisite for quality of delivery (Muse & McManus, 2013). However, for an intervention to achieve its desired outcomes, components of the intervention need to be delivered, and also delivered well. The next step is therefore to develop an equivalent method for assessing the quality with which smoking cessation behavioural support interventions are delivered in clinical practice, and to relate extent of implementation to outcomes (Durlak, 1998).

Failure to deliver an intervention competently has been recognised as a significant barrier to transferring evidence-based findings into clinical practice (Dewing et al., 2013). Specifying the components of an intervention, verifying that they are delivered and delivered well, is basic, sound, clinical and research practice (Santacroce, Maccarelli, & Grey, 2004). Healthcare systems invest considerable resources into quality improvement efforts that aim to optimise the care delivered, in order to maximise effective outcomes and minimise the delivery of ineffective interventions (J. Grimshaw et al., 2006). It is therefore necessary to ensure reliable methods are established to monitor the quality with which interventions are delivered (Muse & McManus, 2013).

In order to measure quality, it is necessary to first clearly define it. Despite the importance of assessing quality of delivery, the concept of quality is rarely explicitly defined or operationalized, and consequently, there is a lack of standard definitions or methods for measuring quality. One definition of quality of care is: ‘the extent to which health services are consistent with professional standards and increase the likelihood of desired outcomes’ (APA, 2007). Monitoring quality of care is often referred to as ‘quality assurance,’ which involves ‘evaluating healthcare services in terms of effectiveness, appropriateness, acceptability, adequacy, duration and outcome’ (APA, 2007). Quality of care is closely related to the the notion of ‘competence’ (sometimes referred to as ‘competency’), which refers to the knowledge and skills of healthcare professionals delivering interventions (Waltz, Addis, Koerner, & Jacobson, 1993). Specifically, competence has been defined as: ‘the degrees to which intervention providers display the general and intervention-specific, evidence-based, knowledge and skills required to appropriately deliver an intervention’ (Muse & McManus, 2013). Thus competences represent ‘professional standards,’ and examining the extent to which intervention providers competently deliver interventions is one means through which quality may be assessed.

Measuring competence is not straightforward given the complexity of skills required to deliver behaviour change interventions and the potential for tailoring interventions to participants and/or contexts (Santacroce et al., 2004). In the psychotherapy literature, there are numerous examples of strategies for assessing the competences with which interventions, such as cognitive behavioural therapy (CBT), are delivered (Barber, Sharpless, Klostermann, & McCarthy, 2007). A systematic review of methods for assessing competence for delivering CBT identified ten

assessment methods, which broadly fell into four categories (Miller, 1990; Muse & McManus, 2013):

1. *Knowledge base assessments*, which evaluate the extent to which intervention providers have the relevant knowledge to deliver an intervention. This may be assessed, for instance, through multiple-choice question (MCQ) assessments, such as the cognitive therapy awareness scale (CTAS) (Myles & Milne, 2001) or ‘CBT Knowledge Quiz’ (Wright et al., 2002).
2. *Assessments of practical understanding*, that is, understanding of how to apply knowledge and evidence to inform practice. This may be assessed through essays, vignettes, or case reports, such as the ‘video assessment task’ where therapists observe a session dialogue and respond to questions regarding symptom identification and potential CBT techniques to use in treatment (Myles & Milne, 2001).
3. *Assessments of therapists’ practical application of knowledge and skills*, which is often done using role-plays to assess clinical competence. An example of this is the objective structured clinical examinations (OSCEs) used in medical training, where medical trainees engage in a series of role-plays demonstrating brief encounters with standardised patients, and have their performance assessed by independent observers (Epstein & Hundert, 2002).
4. *Clinical practice assessments*, which typically involve assessor-rated treatment sessions. In these types of assessments, therapists are observed when delivering sessions in clinical practice, and have their performance rated using standardised scales, such as the ‘cognitive therapy adherence and competence scale’ (CTACS) (Barber et al., 2007; Muse & McManus, 2013).

Assessment requires a detailed description of the specific strategies, behaviours, or competences that are necessary to optimally deliver an intervention (H. Davies & Crombie, 1995). A set of competences for delivering CBT has been identified following a systematic, evidence-based method (Roth & Pilling, 2008). These competences have been presented in a framework, organised into five over-arching classification groups: (1) generic competences; (2) basic behavioural and cognitive therapy competences; (3) specific behavioural and cognitive therapy techniques; (4) problem-specific competences, and (5) metacompetences (Roth & Pilling, 2008). In the domain of smoking cessation, the taxonomy of smoking cessation BCTs (Michie, Hyder, Walia, & West, 2011), has been applied to specify the components of guidance documents and published descriptions of effective behavioural support interventions, which in turn served as a basis for identifying evidence-based competences for delivering individual- and group-based smoking cessation behavioural support (Michie, Churchill, & West, 2011). In total 94 distinct competences for delivering behavioural support for smoking cessation were identified, of which 59 featured across at least two guidance documents. Competences were grouped according to their behaviour change function: boost motivation, maximise self-regulatory capacity and skills, promote adjuvant activities, and general aspects of the interaction. Fourteen individual and three group behavioural support competences were supported by evidence from trials demonstrating effective interventions, and were thus classed as evidence-based (Michie, Churchill, et al., 2011). These identified competences have subsequently informed the content of a national knowledge and skills training and accreditation program developed by the National Centre for Smoking Cessation Training (NCSCT), as well as guidance documents, such as the NCSCT training standard and learning outcomes for training Stop Smoking Practitioners (www.ncsct.co.uk) (West, Lorencatto, et al., 2010). In the United States, the Association for the Treatment of

Tobacco Use and Dependence (ATTUD) has also developed a similar framework of 45 evidence-based competences for the treatment of tobacco dependence (ATTUD, 2005). These sets of evidence-based competences represent criteria and indicators (i.e. professional standards) against which delivery of an intervention may be compared.

A second step in assessing competence is to observe multiple intervention sessions and rate intervention provider skills, preferably using a scale with demonstrated inter-rater reliability (Davies & Crombie, 1995; Muse & McManus, 2013). Such scales have been developed for specific types of intervention. For example, a five-point scale, the ‘motivational interviewing treatment integrity code’ (MITI), has been applied to assess lay counsellors’ competence for delivering a motivational-interviewing type intervention for increasing adherence to anti-retroviral medication delivered in public health clinics in South Africa (Dewing et al. 2013). Lay counsellors were observed via audio-recorded intervention sessions, and their competence for delivering the intervention assessed in terms of the following aspects of the clinical interaction: evocation, collaboration, autonomy, support, direction, and empathy (Dewing et al., 2013; Moyers, 2010). Using this scale, the lay counsellors were found to lack competence in delivering motivational interviewing (Dewing et al., 2013). A reliable five-point scale for rating quality of delivery of two types of interventions targeting excessive alcohol use has been developed, with ratings ranging from 1 (not at all) to 5 (very well) (Tober, Clyne, Finnegan, Farrin, & Russell, 2008). Application of this scale to video-recordings of intervention sessions found that the scale could reliably distinguish between both interventions on the grounds of quality ratings, and between therapists providing the intervention, which were classified as demonstrating either ‘high,’ ‘medium,’ or ‘low’ quality of delivery (Tober et al., 2008).

In the domain of smoking cessation, the NCSCT evidence-based online knowledge and skills training program involves a baseline assessment of Stop Smoking Practitioners' knowledge and practical understanding of how to deliver smoking cessation behavioural support (Brose, West, et al., 2012). An evaluation of this program demonstrated that completing the training significantly improved practitioners' knowledge and practical understanding of how to deliver evidence-based behavioural support, even amongst more experienced practitioners (Brose, West, et al., 2012). However, knowledge and practical understanding do not necessarily translate into performance; there is thus a need to base competence assessments on a more nuanced assessment of how well particular competences are actually demonstrated and delivered.

There has been some work developing methods for rating the competence with which particular smoking cessation intervention BCTs , such as 'goal-setting,' or 'maximising motivation to quit,' are delivered. One example is a six-point rating scale applied to transcripts of audio-recorded sessions of an intervention aimed at reducing smoking through increasing exercise (i.e. Exercise Assisted Reduction in Smoking- EARS, trial) (Figure 11) (Thompson et al., In press)

Figure 11. Scoring system of EARS trial competence rating scale (Thompson et al. In press).

Competence level*	Scoring	Examples
Incompetent	0	Absence of feature and /or highly inappropriate performance
Novice	1	Minimal use of feature and /or inappropriate performance,
Advanced beginner	2	Evidence of competence, but numerous problems
Competent	3	Competent, but some problems or inconsistencies
Proficient	4	Good features, but minor problems or inconsistencies
Expert	5	Very good features, minimal problems or inconsistencies
	6	Excellent performance

This scale assesses both whether or not intervention components were delivered (i.e. fidelity), as well as the competence with which components are delivered (i.e. quality). To support the rating of sessions using this scale, a description of the key components of each technique that are required for its optimal delivery is provided. This represents, to our knowledge, the first attempt to systematically assess the quality with which components of smoking cessation behaviour change interventions are delivered. Although a useful first step, the EARS scale was piloted on a limited number of audio-recordings of intervention sessions (n= 36), and the inter-rater reliability of the scale was not assessed. This scale was developed for use in the process evaluation of a research trial; there is a need to establish similar methods for monitoring the quality with which smoking cessation interventions are implemented in the context of actual clinical practice.

In addition to developing a scale for monitoring the quality of delivery of smoking cessation behavioural support in practice, it is also important to examine the extent to which implementation is associated with outcomes. This is the final, fourth, stage of Durlak’s

implementation assessment approach: ‘*relate implementation to outcome.*’ (see Chapter 1.4.4., General Introduction) (Durlak,1998). Intervention outcomes have been embedded in definitions of quality of care (APA, 2007), and are often used as proxy measurements of the quality with which interventions are delivered; the argument being that better outcomes result from well delivered interventions (Davies & Crombie, 1995). However, quality cannot be defined or measured solely in terms of outcomes, as poor outcomes may occur despite high quality care, and positive outcomes may occur despite poor quality care (Chassin & Galvin, 1998). Despite the importance of examining the relationship between quality and outcomes, a review of the evidences suggests that the association between extent of implementation and outcomes is very rarely examined (Borrelli, 2011; Dane & Schneider, 1998; Durlak & DuPre, 2008). Where this has been assessed, evidence suggests that better intervention outcomes are associated with improved implementation (Durlak, 1998; Durlak & DuPre, 2008). There is also evidence to suggest that variation in therapist performance when delivering CBT is a significant factor in explaining treatment outcomes, particularly, for evidence-based therapies implemented in routine clinical settings (G. S. Brown, Lambert, Jones, & Minami, 2005; Muse & McManus, 2013; Okiishi et al., 2006; Roth & Pilling, 2008). However, the extent to which implementation of smoking cessation behavioural support interventions is associated with intervention outcomes is unknown.

The principal aims of the present study were to:

1. Develop a method for rating the quality of delivery of one key BCT, ‘goal-setting’, within behavioural support for smoking cessation;
2. Examine the association between quality of delivery of this BCT and outcome.

Goal-setting typically involves setting a quit date with the smoker, which is the date on which the smoker will initiate their quit attempt and engage in complete abstinence from that point onwards (West & Stapleton, 2008). There is both a theoretical and empirical rationale for focusing on goal-setting as a key technique. PRIME theory of motivation argues that continuous self-regulation is integral to successfully quitting smoking, in that ex-smokers have to maintain their resolve not to smoke in response to smoking cues, and employ strategies to cope with urges and withdrawal symptoms in order to prevent relapse (West, 2009). Control theory proposes that goal-setting is central to self-regulation; setting goals, monitoring behaviour, receiving feedback, and reviewing relevant goals in light of feedback are all components of self-management and behavioural control (Carver & Scheier, 1982). Goal-setting has also been identified as an evidence-based BCT for delivering individual smoking cessation behavioural support (Michie, Churchill, et al., 2011). To date, the association between individual smoking cessation BCTs and quit outcomes has only been assessed by examining which component BCTs feature in effective behavioural support evaluation trials (Lorencatto, West & Michie, 2012; Michie, Churchill, & West, 2011), and which BCTs featured in NHS Stop Smoking Service treatment manuals are associated with improved quit rates; with manuals serving as a proxy indicator of what is intended to be delivered in practice (West et al. 2010; West et al. 2011). In other domains, the delivery of goal-setting as part of a type 2 diabetes intervention has been associated with significant ($\geq 5\%$) reduction in body mass index (Hankonen, Sutton, Simmons, Prevost, & Hardeman, 2013). The extent to which goal-setting as actually delivered is associated with outcomes of smoking cessation behavioural support interventions in practice is unknown.

To address the second study aim, the outcome measure will be the likelihood of smokers making a quit attempt as planned. Setting a quit date is an example of an initial ‘sub-goal’ of the over-

arching goal of behavioural support interventions, which is to successfully quit smoking long-term (Borrelli & Mermelstein, 1994). Setting this sub-goal involves making an initial, committed, intention to stop smoking and a plan for achieving this, such as a smoker agreeing to and planning to quit smoking completely on a specific date (i.e. their quit date) (Borrelli & Mermelstein, 1994). This is an example of an evidence based technique, “if-then plans”, referred to as an implementation intention (Gollwitzer, 1993; Webb & Sheeran, 2008). Attainment of this ‘sub-goal’ involves the smoker making a quit attempt on their planned quit date. However, there is evidence to indicate that although individuals may set a goal, and intend to engage in the target behaviour change, this is not always achieved (i.e. intention-behaviour gap) (Sheeran, 2002; Sheeran, Webb, & Gollwitzer, 2005). The extent to which the quality with which a Stop Smoking Practitioner facilitates the process of setting a quit date with the smoker influences the subsequent likelihood of the smoker enacting a quit attempt on their planned quit date is unknown.

This exploratory study will develop and pilot a method for assessing the quality of goal-setting in smoking cessation behavioural support interventions delivered in clinical practice by a UK national telephone quit-line service. ‘Quality’ will be operationalized as the ‘*appropriate and comprehensive*’ delivery of the BCT ‘facilitate goal-setting.’ Quality will be assessed using a recommended two-staged, clinical practice assessment approach (Davies & Crombie 1995), whereby the components of appropriate and comprehensive goal-setting will be specified, and the competent delivery of these components in practice by Stop Smoking Practitioners verified by examining transcripts of audio-recorded behavioural support sessions. The association between quality of goal-setting and the likelihood of smokers enacting a quit attempt as planned will be examined.

7.1.1. Aims and Objectives

The specific aims and objectives are to:

1. Specify the components of appropriate and comprehensive goal-setting for smoking cessation behavioural support, as a basis for formulating a scale for rating quality of goal-setting.
2. Assess the inter-rater reliability of the developed scale when applied to evaluate quality of goal-setting in delivered behavioural support sessions.
3. Examine the association between quality of goal-setting and the likelihood of smokers making a quit attempt as planned. This will be examined according to:
 - i) The overall composite score for quality of goal-setting based on the developed scale;
 - ii) The individual identified scale components.

7.2. Methods

Ethical approval

This study received ethical approval by the Clinical, Educational, and Health Psychology Research Department Ethics Committee (UCL) [Reference: CEHP/2011/038].

Design

This cross-sectional evaluative study was conducted in two stages: 1) development and piloting of a quality of goal-setting rating scale; and 2) examination of the association between quality of goal-setting in smoking cessation behavioural support interventions delivered in practice and subsequent enactment of quit attempts as planned.

7.2.1. Stage 1: Development and piloting of the Quality of Goal-setting Rating Scale

Sample and Materials

To specify the components of appropriate and comprehensive goal-setting, three national guidance documents were identified: (1) the National Centre for Smoking Cessation and Training (NCSCT) ‘Standard Treatment Programme’; (2) The NCSCT ‘Training Standard: Learning Outcomes for Training Stop Smoking Practitioners;’ and (3) The curriculum of the NCSCT’s knowledge and skills training and accreditation program (see <http://www.ncsct.co.uk>) (Brose, West, Michie, & McEwen, 2013; West, Lorencatto, et al., 2010). The content of these guidance documents is founded on systematically identified evidence-based BCTs and competences for the delivery of effective smoking cessation behavioural support (Michie, Churchill, et al., 2011; West, Evans, & Michie, 2011; West, Walia, Hyder, Shahab, & Michie, 2010). Collectively, these guidance documents outline the recommend format and content of

optimal, evidence-based smoking cessation behavioural support (i.e. professional standards). A fourth document was also sourced: the UK national telephone quit-line service treatment manual. This document specifies the content, format and procedures that all Stop Smoking Practitioners operating within the service being examined are expected to adhere to when delivering behavioural support to *all* smokers.

To conduct a clinical practice assessment of the extent to which components of competent goal-setting are delivered in practice appropriately and comprehensively, a set of opportunistically collected audio-recordings of pre-quit behavioural support sessions were obtained from a UK national telephone quit-line service. This service offers dedicated, telephone-based behavioural support over four sessions: one pre-quit session, one quit-day session and two post-quit sessions. The service also offers pharmacological support in the form of nicotine replacement therapy vouchers that are mailed to smokers. Behavioural support is delivered by six dedicated Stop Smoking Practitioners that have on average 13.5 years of experience working as a dedicated Stop Smoking Practitioner (range: 13-15), with the majority having passed the NCSCT's skills and knowledge training program (n=5 practitioners). In 2011, the service had an average self-reported four-week successful quit rate of 51.8%. A total of 110 pre-quit sessions consecutively delivered to 110 consenting smokers were audio-recorded during an eight month data collection period. This minimised the risk of practitioners selecting particular smokers or sessions to audio-record. Informed consent to have the session audio-recorded was obtained from both the practitioner and smoker at the start of the session. Only pre-quit behavioural support sessions were examined as it is typically during this session, and stage in the quit attempt, that smokers agree to make a commitment to setting a quit date during a discussion with a Stop Smoking Practitioner. This quit date is typically within 1 to 2 weeks of the pre-quit session, prior to or on

the date of the following session (i.e. quit-day session). Of the 110 audio-recorded sessions, 11 were excluded as they were incomplete. Furthermore, only the sessions of smokers who expressed an interest and willingness to set a quit date during their pre-quit session were examined, as it would be inappropriate to expect a practitioner to set a quit date with a smoker who, following discussion, decided that s/he explicitly did not wish to commit to making a quit attempt at this point in time. On this basis, a further 14 smokers were excluded. Therefore, a final sample of 85 opportunistically collected audio-recordings of pre-quit sessions delivered to smokers willing to set a quit date was used for assessing clinical practice. All audio-recordings were transcribed verbatim and fully anonymised.

Procedure

Two researchers first independently analysed the three guidance documents and service treatment manuals to specify optimal goal-setting. This was done by applying a reliable taxonomy of BCTs (Michie et al. 2011) to guide the identification and characterisation of components present in guidance document descriptions regarding what constitutes quality goal-setting for smoking cessation behavioural support. Those components identified across all four documents with agreement by both researchers were selected as items to form the basis of the content of a quality rating scale. Identified components were extracted from each document and tabulated. Seven components contributing to appropriate and comprehensive goal-setting were identified, alongside three components representing activities that result in inappropriate goal-setting; producing a 10-item quality of goal-setting rating scale (QGRS) (see Figure 12). Scoring using this scale is conducted by allocating points for the delivery of each appropriate component, and deducting points for delivery of inappropriate components; potential overall quality of goal-setting scores therefore range from -3 (i.e. delivery solely of inappropriate goal-setting

components) to 7 (i.e. comprehensive delivery of all components of appropriate goal-setting). Higher scores represent higher quality goal-setting. To facilitate and promote consistency in scoring, a brief description of optimal goal-setting, based on descriptions from guidance documents and scale components, was provided above the scale for guidance (Figure 12).

Figure 12. The Quality of Goal-setting Rating Scale (QGRS)

Assessing quality of goal-setting for smoking cessation behavioural support

Key features: Help the smoker to set a quit date and goals that support the aim of remaining abstinent.

Components of competent goal-setting: The practitioner should prompt the smoker to set a quit date. The practitioner should then work collaboratively with the smoker to agree upon a suitable quit date. The assigned quit date should be a clear date (i.e. dd/mm/yy), linked to a clear time frame within the near future, ideally within 1-2 weeks following the initial pre-quit session, and should allow sufficient time for the smoker to obtain any smoking cessation medications they plan to use during the quit attempt. The practitioner should outline the rationale as to why gradual cessation/cutting down does not work, and encourage the smoker to smoke as normal up until the agreed quit date. It should be clearly emphasized to the smoker that the goal is not to smoke a single cigarette after the quit date, not even a single puff. The practitioner should support these explanations with examples and normative information as to what other smokers' found helpful when setting a quit date.

Scoring: Score 0 if goal-setting is completely absent in the content of behavioural support delivered by the practitioner. Additional points are to be incrementally allocated for the delivery of components representing appropriate goal-setting (+). Points are to be deducted for the delivery of components contributing to inappropriate goal-setting (-1). Possible score range: -3 to 7.

- | | |
|----|--|
| 0 | Absence of goal-setting |
| +1 | Prompts goal-setting (i.e. encourages smoker to set a quit date) |
| +1 | Agreed quit date is a clear date (i.e. dd/mm/yy) |
| +1 | Agreed quit date is within an appropriate time frame (i.e. within 1-2 weeks of pre-quit session) |
| +1 | Practitioner takes into account time taken to obtain medication when selecting an appropriate quit date. |
| +1 | Provides advice as to why cutting down does not work |
| +1 | Emphasises that the goal is not to smoke a single cigarette after the quit date, not even a single puff |
| +1 | Provides relevant normative information and examples (i.e. what other smokers' have found helpful when setting a quit date, research findings regarding effectiveness of suggested behavioural strategies and medications). |
| -1 | Inappropriate goal-setting [i.e. not a clear quit date (i.e. dd/mm/yy), not within 1-2 weeks of pre-quit session and/or does not allow sufficient time for smoker to obtain medication] |
| -1 | Encourages or reinforcing cutting down |
| -1 | Practitioner undermines the smoker's commitment to the quit date (e.g. implies flexibility in agreed quit date, suggests that it is ultimately up to the smoker whether they decide to go through with the quit date or not) |

The QGRS was piloted on 85 transcripts of pre-quit behavioural support sessions to assess clinical practice. Two researchers with extensive previous experience of specifying the content of transcripts of audio-recorded behavioural support sessions identified and extracted the relevant segment from each transcript in which the discussion between the practitioner and smoker related to setting a quit date. These excerpts were then independently scored using the QGRS to assess how competently practitioners facilitated the process of setting a quit date with the smoker.

Analyses

All excerpts were double-coded by two independent researchers in order to assess the extent to which quality scores assigned using the QGRS were reliable. Inter-rater reliability was assessed using Weighted Cohen's Kappa, which adjusts for distances between scores when calculating agreement based on scales that are not dichotomous (i.e. score range: -3 to 7 as opposed to 0 or 1) (Cohen, 1968). Disagreements were resolved through discussion or consultation with a behaviour change expert. The agreed quality score for each transcript was recorded.

7.2.2. Stage 2: Evaluation of the association between quality of goal-setting and enactment of quit attempts as planned

Sample and Procedure

A power calculation was not conducted to determine the optimal sample size for this study given the exploratory nature of the study and the fact that session transcripts were collected opportunistically within an eight-month data collection window. Therefore, the same set of opportunistically collected 85 transcripts of audio-recorded pre-quit behavioural support sessions, which were scored for quality of goal-setting in Stage 1, were used in Stage 2 to assess

the association between quality of goal-setting and enactment of quit attempts. For each of the 85 smokers, anonymised outcome data were obtained from the telephone quit-line service as to whether or not the smoker subsequently made a quit attempt as planned on their quit date; this was assessed at the follow-up quit day session by practitioners via smoker self-report. Therefore, the main outcome measure was a dichotomous: ‘yes’ the smoker enacted a quit attempt and was not currently smoking vs. ‘no’ the smoker failed to enact a quit attempt and was still smoking. Anonymised information on demographic and smoker characteristics, such as cigarettes per day or time to first cigarette, was collected for each smoker by the Stop Smoking Practitioner using a standardised smoker record and service monitoring form during the routine intake assessment in the pre-quit session.

Analyses

The mean quality of goal-setting score for smokers who did and did not make a quit attempt as planned was calculated. For the main analysis, a two-level logistic regression model was used to examine the extent to which quality of goal-setting scores predicted the likelihood of smokers enacting a quit attempt as planned. Multi-level logistic regression analyses were used to account for clustering that may occur because quit attempts delivered by the same Stop Smoking Practitioner are likely to share some similarities. Thus, level 1 was the individual smoker’s treatment episode, and level 2 was the individual Stop Smoking Practitioner that set the quit date with smoker. Smokers lost to follow-up by the second session were treated as still smoking and therefore classed as not having made a quit attempt; this is standard practice given that loss to follow-up is closely associated with resumption of smoking (West, Hajek, Stead, & Stapleton, 2005). Analyses were conducted in MLwiN version 2.14.

To identify whether individual components of the 10-item scale independently contributed to any observed associations between goal-setting and the likelihood of quit attempt enactment, each scale item was first scored as being present or absent in each transcript (see Figure 12 for items). The above multi-level logistic regression analyses were then repeated using each item from the scale as a separate predictor variable. This additional analysis was only done for scale items that displayed some variability in the outcome measure (i.e. item was identified in transcripts of smokers who did *and* did not make a quit attempt), and for items that were identified as present in at least 10 transcripts in order to ensure a minimum frequency.

The associations between each smoker demographic and smoker characteristic with the outcome (i.e. enactment of quit attempts) and predictor variables (i.e. quality of goal-setting) were examined using t-tests, chi-square analyses, and ANOVAs as appropriate in order to identify any potential confounding variables that would need to be controlled for in the multi-level logistic regression analyses.

7.3. Results

1. Outcome

At follow-up, only 18 of the 85 smokers (21.2%) reported enacting a quit attempt as planned, with the rest still reported to be currently smoking. The demographic and smoker characteristics of the smokers are presented Table 16. There were no significant differences in the characteristics of smokers that did and did not make a quit attempt and no smoker demographic or smoker characteristics were shown to be separately associated significantly with the predictor or outcome variables

Table 16. Smoker characteristics, presented overall and by outcome.

	Overall Sample (n=85)	No Quit Attempt (n=67; 78.8%)	Quit Attempt (n=18, 21.2%)
Age, M (SD)	44.3 (16.7)	45.2 (16.1)	40.8 (18.9)
Male, % (n)	42.4 (36)	41.8 (28)	44.4 (8)
Occupational Grade, % (n)			
Employed	49.4 (42)	49.3 (33)	55.6 (9)
Unemployed	42.3 (36)	43.2 (29)	38.9(7)
Student	7.1 (6)	7.5 (5)	5.6 (1)
Unable to code	1.2 (1)	-	5.6 (1)
Ethnicity, % (n) ^a			
White British	85.9 (73)	86.4 (57)	88.9 (16)
Any other White Background	9.5 (8)	9.1 (6)	11.1 (2)
Indian	3.5 (3)	4.5 (3)	-
Pharmacological Support, % (n)			
None	21.7 (18)	21.2 (14)	23.5 (4)
Single NRT	20.5 (17)	21.2 (14)	17.6 (3)
Combination NRT	53 (44)	51.5 (34)	58.8 (10)
Champix	4.8 (4)	6.1 (4)	-
Cigarettes per day, M (SD)	17.3 (10.5)	17.0 (9.9)	19 (13.3)
Time to first cigarette, % (n)			
60+ mins	18.3 (15)	16.9 (11)	23.5 (4)
31-60 mins	14.6 (12)	12.3 (8)	23.5 (4)
6-30 mins	40.2 (33)	43.1 (28)	29.4 (5)
< 5 mins	26.8 (22)	27.7 (65)	23.5 (4)
Time spent with urges, % (n)			
None	3.6 (3)	3.0 (2)	5.6 (1)
A little of the time	11.9 (10)	10.6 (7)	16.7 (3)
Some of the time	46.4 (39)	43.9 (29)	50.0 (9)
A lot of the time	28.6 (24)	31.8 (21)	22.2 (4)
Almost all of the time	9.4 (8)	10.6 (7)	5.6 (1)
Strength of urges, % (n)			
No urges	4.8 (4)	4.5 (3)	5.6 (1)
Slight	8.3 (7)	6.1 (4)	16.7 (3)
Moderate	35.7 (30)	36.4 (24)	33.3 (6)
Strong	37.6 (32)	39.4 (26)	33.3 (6)
Extremely Strong	12.9 (11)	13.6 (9)	11.1 (2)
Commitment to quit attempt, % (n)			
Low	3.6 (3)	3.1 (2)	5.9 (1)
Moderate	12.2 (10)	12.3 (8)	11.8 (2)
High	40.2 (33)	40.0 (26)	41.2 (7)
Very high	43.9 (16)	44.6 (29)	41.2 (7)

Confidence in quitting, % (n)				
	Low	12.5 (10)	12.5 (8)	12.5 (2)
	Moderate	36.3 (29)	34.4 (22)	43.8 (7)
	High	30 (24)	34.4 (22)	12.5 (2)
	Very high	21.3 (17)	18.8 (12)	31.3 (5)
Weeks since most recent quit attempt, M (SD)		92.3 (158.1)	84.3 (144.47)	118.2 (199.9)
Length of most recent quit attempt, M (SD)		10.1 (16.8)	9.1 (12.7)	14.2 (28.1)

M: Mean; SD: Standard deviation; NRT: Nicotine replacement therapy.

^a Ethnicity is self-reported using the standard UK Census (2001) categories

2. *Piloting of the QGRS*

The weighted Cohen's Kappa value for agreement between raters when scoring all 85 session transcripts using the QGRS was 0.68, representing 'substantial' agreement (Landis & Koch, 1977). Across all smokers, the average quality score was 1.6 (SD 1.2; range: -1 to 5); given the range of possible scores (i.e. -3 to 7), this average score represents 'low' quality of goal-setting. The average quality score for smokers that made a quit attempt as planned was 2.2 (SD .70; range: 1 to 4), and 1.4 (SD 1.27; range: -1 to 5) in smokers who did not make a quit attempt as planned.

3. *Association between overall quality of goal-setting and enactment of quit attempts*

Higher overall quality of goal-setting in pre-quit sessions was shown to be significantly associated with an increased likelihood of smokers enacting a quit attempt as planned ($p < .001$, OR 2.60, 95% CI: 1.54 to 4.40).

4. *Association between individual components of the developed quality scale and enactment of quit attempts*

Of the 10 identified components included in the developed quality rating scale, each component was identified on average in 29 transcripts (range: 2 to 85) (Table 17). Only five components were identified in at least 10 sessions and had sufficient variability in the quit attempt outcome variable to enable an examination of their independent association with quit attempts (Table 17). Of these, only one component was found to be independently associated significantly with an increased likelihood of smokers making a quit attempt as planned: '*set a*

clear quit date with the smoker (i.e. dd/mm/yy)' ($p < .001$, OR 36.9, 95% CI: 4.52 to 302.11). The converse of this, '*inappropriate goal-setting*' (i.e. setting an unclear quit date, within inappropriate time frame, or not permissive of sufficient time to obtain medications),' was found to be independently associated significantly with a decreased likelihood of smokers making a quit attempt as planned ($p < .001$, OR 0.3, 95% CI: .003 to .24) (Table 2)

Table 17. Association between individual scale components and quit attempts

Scale Component	Frequency ^a (n transcripts; max=85)	Odds Ratio	95% Confidence Interval	p-value
Prompt goal-setting ^b	85	-	-	-
Set a clear quit date (dd/mm/yy)	40	36.9	4.52 to 302.11	p<.001
Set appropriate quit date (time frame within 1-2 weeks of pre-quit session) ^c	52	-	-	-
Considers time taken to obtain medication when setting quit date	30	.75	.15 to 3.78	p=.33
Advise against cutting down	5	-	-	-
Emphasise 'not a puff'	5	-	-	-
Provide normative information	11	.57	.18 to 3.78	p=.72
Inappropriate goal- setting (i.e. not clear date, + 2 weeks away from pre-quit session)	44	.03	.003 to .24	p<.001
Encourage cutting down	2	-	-	-
Undermine commitment to quit attempt (i.e. imply flexibility in quit date)	20	.833	.24 to 2.88	p= .77

^a Multi-level analyses only conducted for scale components with identified in a minimum of 10 transcripts.

^b Multi-level analysis not conducted for this scale component as received by all smokers (i.e. no variability in predictor variable)

^c Multi-level analysis not conducted for this scale component as no variability in outcome for this component

7.4. Discussion

A reliable 10-point scale based on evidence-based guidance documents was developed and piloted to assess quality of delivering a key BCT- ‘goal-setting,’ in behavioural support interventions delivered in clinical practice. This allowed the exploration of its association with outcome, with the finding that there was a nearly three-fold increase in the likelihood of smokers making a quit attempt as planned when goal-setting was appropriately and comprehensively delivered. The levels of reliability achieved for this QGRS are in line with those observed for competence assessment methods for interventions in other domains, such as psychotherapy and reducing excessive alcohol use (Muse & McManus, 2013; Tober et al. 2009). The establishment of this reliable method for scoring quality of goal-setting builds upon previous work examining competence in delivering smoking cessation behaviour change interventions by extending existing assessments methods beyond the knowledge based competence assessments (Brose, West, Michie, & McEwen, 2013), or the context of research (Thompson et al. *In press*), to actual performance in the context of clinical practice. This is important given that evidence-based behavioural support interventions for smoking cessation are increasingly implemented in wider clinical practice (Raw et al. 2009). The QGRS also builds on previous work reported in this thesis, which demonstrated the reliability of recently developed methods for assessing the fidelity of delivery of smoking cessation behavioural support interventions (Lorenatto, West, Christopherson, & Michie, 2013). Together, these assessment methods provide a set of reliable tools for examining *how much* alongside *how well* the content of complex behavioural support interventions are delivered in practice, that is, both fidelity and quality of delivery. This in turn serves as a method for more comprehensively monitoring the implementation of these evidence-based interventions in clinical practice.

Application of the QGRS to examine quality of goal-setting in a sample of pre-quit sessions delivered by a UK national telephone quit-line service demonstrated that, on average, Stop Smoking Practitioners within this service were not competently facilitating the process of setting a quit date with smokers who were interested and willing to set a quit date. Indeed, average quality scores were classified as low, which is consistent with findings from behaviour change interventions in other domains, such as improving medication adherence, which find that intervention providers often fail to achieve competence in delivering intervention components (Dewing et al. 2013). ‘Facilitating goal-setting’ is recognised as an evidence-based BCT for smoking cessation behavioural support interventions (Michie, Churchill, & West, 2011). Although practitioners delivered this manual-specified BCT to all clients (i.e. 100% fidelity), the quality with which they delivered it was low and variable. This highlights that although fidelity is important and a pre-requisite for quality, on its own, it is insufficient. The observed low quality of goal-setting in a national telephone quit-line service represents an aspect of poor implementation and an area of service provision requiring improvement- a training need, that may be fed back to practitioners and inform future training or professional development courses.

The nearly three-fold increase in the likelihood of smokers making a quit attempt as planned with higher quality of delivery of goal-setting is consistent with previous studies and systematic reviews, which demonstrate that better implementation is often associated with better intervention outcomes (Durlak, 1998; Durlak, 2002; Dane & Schneider, 1998; Muse & McManus, 2013). Previous examination of the association between individual smoking cessation BCTs and intervention outcomes have utilised published reports of effective trials and the content of NHS Stop Smoking Service treatment manuals as proxy indicators as to what was delivered in the intervention (Michie, Churchill, et al., 2011; West, Walia, et al., 2010). Goal-

setting has been found to feature in multiple effective randomized controlled trials of individual smoking cessation behavioural support interventions (Michie, Churchill, & West, 2011). The present study builds on this work by demonstrating the association of an individual BCT with an intervention outcome in the context of what is actually delivered in clinical practice, rather than intended or recommended in manuals. The observed findings also demonstrate the effectiveness of goal-setting in a new context, that of actual clinical practice, and therefore adds to its existing evidence-base.

Exploring the association between individual components and likelihood of quit attempts revealed that two linked components were independently associated with quit attempts: ‘setting a clear quit date,’ which increased the likelihood of quit attempts, and the converse, ‘setting an inappropriate quit date,’ which decreased the likelihood of quit attempts significantly. This analysis demonstrates how a complex BCT may be broken down into sub-components to identify the ‘active ingredients,’ that contribute outcomes. Proponents of a more flexible approach to fidelity of delivery argue that strict fidelity should only be expected when delivering those intervention components deemed essential or unique, with a degree of permissible flexibility in the delivery of components that are acceptable to the intervention, but not necessarily essential or unique (Collins et al., 2009; Waltz et al., 1993). Given the present finding, it could be argued that emphasis should be placed on ensuring Stop Smoking Practitioners consistently deliver the specific components of BCTs that are known to contribute to effective outcomes (i.e. set a clear quit date), with the remaining components that have a less established evidence-base (i.e. remaining 8 scale components) being acceptable, and recommended, for delivery, but not necessarily deemed essential. Setting a quit date with a smoker that is on a clear date (i.e. Monday, July 29th), as opposed to an unclear date (i.e. in 2 weeks’ time), is arguably a simple

procedure to do, but with a demonstrated potential to make a significant contribution to the likelihood of whether a smoker will actually make an attempt to stop smoking. Future feedback should ensure practitioners are informed of the evidence about the goal-setting components, and future training should aim to equip practitioners with the necessary skill to competently deliver these components.

Furthermore, the present findings also provide insight into an additional dimension of the five-part model of intervention fidelity- *enactment* of the intervention by its recipients (Borrelli, 2011). During the pre-quit session, all clients expressed a willingness to set a quit-date and subsequently committed to an agreed quit date. Yet the majority of clients failed to actually attain this initial sub-goal by going on to make a quit attempt as planned. The failure of intervention recipients to enact a delivered, evidence-based BCT highlights an issue in the later stages of the translational implementation process, and an ‘intention-behaviour’ gap. Systematic reviews of behaviour change interventions across domains have demonstrated that intention to change target behaviours does not always translate into actual behaviour change (Gollwitzer, Sheeran, Michalski, & Seifert, 2009; Sheeran, 2002; Sheeran et al., 2005). Although it was found that higher quality of goal-setting was associated with increased likelihood of clients enacting their quit attempt as planned (i.e. lessened intention-behaviour gap), it is necessary to consider instead whether factors relating to the characteristics or behaviour of clients who failed to enact the quit attempt influenced the clinical interaction and the Stop Smoking Practitioner’s delivery of the BCT, or the smokers’ subsequent goal-attainment. It has been demonstrated that aspects of personality, the strength, activation, and self-concordance of superordinate goals, and the presence of behavioural self-regulatory problems moderate the effects of forming an implementation intention on goal attainment (Webb & Sheeran, 2008). Whether any of these

factors moderated the relationship between quality of goal-setting and smokers' subsequent enactment of planned quit dates is unclear and should be examined in future research.

In addition, to form an implementation intention (i.e. set a goal), the individual must first identify a suitable opportunity to attain their desired goal (i.e. when/where/how). Clearly specifying this opportunity renders it cognitively more accessible and activated, in turn increasing the likelihood that the anticipated opportunity will be detected and acted on as intended (i.e. goal-attainment) (Webb & Sheeran, 2008). In a meta-analysis, increased accessibility of the components of an implementation intention plan has been shown to mediate the effect of forming an implementation intention on subsequent goal attainment, whereas deliberative processes, such as intention and/or self-efficacy related to goal attainment, did not (Webb & Sheeran, 2008). In the context of the present findings, setting a clear quit date with a smoker on a precisely specified date is one component of the goal-setting implementation intention that serves to improve specificity and heightens the accessibility of the intended quit date. This in turn increases the likelihood of the smoker enacting the quit attempt on the specified date when it arrives. Conversely, setting an unclear date (i.e. in 2 weeks' time), is an example of a poorly specified implementation intention with low accessibility, which could potentially result in failed enactment and goal-attainment. This further underlines the need to ensure practitioners are trained to competently set a clear quit date with the smoker, and also highlights factors influencing the likelihood of intervention recipients enacting the planned behaviour change.

A limitation of this study is that outcome data on whether smokers enacted a quit attempt relied on smoker self-report, which may be inaccurate given findings from systematic reviews of discrepancies between self-reported and bio-chemically validated smoking status (Connor Gorber, Schofield-Hurwitz, Hardt, Levasseur, & Tremblay, 2009). In England, self-reported

cigarette smoking prevalence, as reported in data from 2003 Health Survey for England, has been shown to significantly under-estimate true tobacco smoking prevalence by 2.8% when subsamples of respondents are subject to biochemical validation of smoking status (i.e. cotinine saliva samples) (West, Zatonski, Przewozniak, & Jarvis, 2007). A further limitation is that the session transcripts were not coded for the presence of other delivered BCTs. It is possible that other delivered BCTs, or combination of BCTs, contributed to the likelihood of smokers enacting a quit attempt, either in their own right, or by supporting the delivery of the technique ‘facilitate goal-setting.’ Moreover, given that this study was exploratory in its nature and that data was collected opportunistically, the resulting sample size was limited, which did not render controlling for confounding variables in analyses feasible. This in turn has a bearing on the confidence with which it is possible to assert that any observed differences in quit attempt enactment are attributable, or related to, variable quality of goal-setting. Therefore, any observed findings arise through association rather than causation. It is also necessary to consider the clinical significance of these findings; if it were possible to establish the numbers needed to treat for the observed effect of quality of goal-setting on quit attempt enactment, it would be possible to ascertain the extent to which clinical effort is rewarded or justified. Therefore, these findings should be interpreted with caution and these caveats should collectively be considered when interpreting the relationship between quality and outcomes.

It is possible to reliably assess the quality with which Stop Smoking Practitioners delivered a key evidence-based BCT in practice, and in turn relate this to intervention outcomes. The extent to which these findings may be generalised to behavioural support interventions delivered in a context other than the single telephone quit-line service examined remains to be determined. There is a need to develop future interventions to improve the consistency and quality with

which complex behaviour change interventions, such as smoking cessation behavioural support, are implemented in clinical practice settings. The QGRS provides a method for assessing the quality of delivery of a single BCT; the extent to which similar scales may be developed for the other evidence-based BCTs in behavioural support for smoking cessation should be examined in future research.

CHAPTER 8: General Discussion

8.1. Summary of findings

The principal aim of this thesis was to examine factors related to the translation of evidence into practice for smoking cessation behavioural support interventions. The specific objectives were:

- 1) To examine the current specification and reporting of smoking cessation behavioural support interventions by:
 - a. Investigating the reliability of behaviour change technique methodology for specifying the evidence-based components of behavioural support for pregnant smokers (Study 1).
 - b. Evaluating the current standard with which the content of smoking cessation behavioural support interventions is reported in published intervention descriptions (Study 2).

- 2) To assess the fidelity and quality with which smoking cessation behavioural support interventions are implemented in clinical practice by:
 - a. Examining the extent to which the BCT taxonomy may be applied to reliably specify the component of behavioural support interventions as delivered in practice (study 3).
 - b. Assessing whether the taxonomy serves a reliable tool for measuring fidelity of delivery of individual face-to-face and telephone-based smoking cessation behavioural support interventions in practice (Studies 4 and 5).
 - c. Developing a method for reliably assessing the quality with which a key intervention component is delivered in practice (i.e. goal-setting) (Study 6).

- 3) To relate the extent of implementation to outcomes by:
 - a. Examining the extent to which quality of goal-setting is associated with the likelihood of clients enacting a planned quit attempt in practice (Study 6).

Well-specified interventions are a pre-requisite for implementation and evaluation, as poorly specified interventions cannot be faithfully delivered or replicated (Michie et al., 2013). To achieve Objective 1a (Study 1), a recently developed taxonomy of smoking cessation BCTs (Michie, Hyder, et al., 2011) was applied as a coding framework to specify the components of effective behavioural support interventions for smoking cessation in pregnancy, as described in published trial reports or protocols where available. It was possible to use the BCT taxonomy to reliably identify and categorise BCTs comprising these interventions. By examining which BCTs featured in effective behavioural support interventions for pregnant smokers, it was possible also to establish a sub-set of 11 evidence-based BCTs used with this population group. This is consistent with previous research which found the taxonomy could be reliably applied as a framework for specifying the components of effective ‘generic’ individual- and group-based behavioural support interventions (Michie, Churchill, et al., 2011; West, Walia, et al., 2010). Comparison of the BCTs identified as evidence-based for smoking cessation in pregnancy with those previously identified as evidence-based for ‘generic’ behavioural support (n=14) (Michie, Churchill, et al., 2011) highlighted substantial overlap between both sets of evidence-based BCTs, with only two BCTs emerging as uniquely evidence-based for smoking cessation in pregnancy: ‘facilitate use of social support’ and ‘provide rewards contingent on smoking cessation.’ The present findings therefore add to the evidence-base for those BCTs common to both sets, and also underline which specific BCTs should potentially form the basis for future evidence-based smoking cessation interventions for pregnant smokers. Behavioural support

interventions for smoking cessation are typically complex, and it is often unclear which specific components comprise effective behavioural support interventions (Dane & Schneider, 1998; Davidson et al., 2003; Glasziou et al., 2008). The present findings therefore also add to the growing body of research that demonstrates the utility and reliability of BCT taxonomies as a methodological approach for overcoming this through the provision of a common language and set of precisely defined BCTs by which to characterise the content of complex interventions.

For effective interventions to influence clinical practice, evidence of effectiveness must first be widely disseminated in published intervention reports, which ideally should conform to recommendations outlined in reporting standards such as CONSORT (Altman et al., 2001; Moher et al., 2001). Standards of reporting were examined in Study 2 (Objective 1b); the BCT taxonomy was used to assess the current reporting practices for several types of smoking cessation behavioural support interventions (i.e. one-to-one, group, telephone, and mental health). The content of trial protocols and corresponding published reports were coded into component BCTs using the BCT taxonomy (Michie, Hyder, et al., 2011), and the number of BCTs identified within each document compared. Significant differences were observed, with on average only 44% of BCTs included in the original trial protocol also being subsequently reported in published intervention descriptions. Under-reporting was observed equally throughout the time period examined (1992-2008) and across BCTs serving different behaviour change functions, indicating no significant patterns of improvement over time or in the systematic omission of specific types of BCTs. The current reporting of smoking cessation behavioural support interventions therefore does not typically conform to published guidelines/standards. This pattern of under-reporting is consistent with findings from studies examining reporting practices in other domains (Dane & Schneider, 1998; Glasziou et al., 2008;

Glenton et al., 2006; Gresham et al., 1993; Moncher & Prinz, 1991; Odom et al., 2003). A second finding that only a small proportion of authors contacted (18%) provided trial protocols highlights the difficulty encountered in trying to access sufficient information regarding intervention content.

To assess the translation of evidence into practice, methods for monitoring the implementation of complex behaviour change interventions as delivered in practice are also required. Although such methods have been developed for behaviour change interventions in other domains, such as physical activity (Hardeman et al., 2008) and excessive alcohol use (Tober et al., 2008), a method for reliably specifying smoking cessation behavioural support as delivered was lacking. Study 3 (Objective 2a) aimed to evaluate the extent to which the taxonomy of smoking cessation BCTs (Michie, Hyder, et al., 2011) may be applied or adapted to reliably specify components of behavioural support interventions as delivered in clinical practice by the NHS Stop Smoking Services. Following minor adaptations, it was found that the taxonomy could be reliably applied to identify and characterise component BCTs in transcripts of audio-recorded behavioural support sessions as delivered in community pharmacy and specialist Stop Smoking Service settings. Prior to Study 3, the BCT taxonomy had only been applied to specify component BCTs in behavioural support interventions as described in published reports, trial protocols, and service treatment manuals (Lorencatto et al., 2012; Lorencatto, West, Stavri, et al., 2013; Michie, Churchill, et al., 2011; West et al., 2011; West, Walia, et al., 2010). The present findings therefore demonstrate how the utility of the taxonomy as a reliable methodological approach may be extended to data from clinical practice. Furthermore, an accompanying manual to train novice coders to reliably apply this method was developed and evaluated. It was found that it is possible to train novice coders to reliably apply the taxonomy to specify components of smoking

cessation behavioural support interventions in practice, supporting the applicability and dissemination of this methodological approach.

The ability to reliably specify the components of interventions as delivered is a first step towards establishing a method to monitor ‘how much of’ (i.e. fidelity of delivery) and ‘how well’ (i.e. quality) an intervention is delivered as intended. Studies 4 and 5 (Objective 2b) aimed to apply the BCT taxonomy as a method for assessing the fidelity of delivery of smoking cessation behavioural support interventions in practice. This was first piloted in Study 4, which applied the BCT taxonomy to specify component BCTs in service treatment manuals and a small number of transcripts of audio-recorded individual, face-to-face, behavioural support sessions delivered by two NHS Stop Smoking Services. Fidelity was quantified by assessing what proportion of manual-specified BCTs was identified in transcripts, and therefore delivered (i.e. % fidelity). In Study 5, these methods were replicated using a larger sample of transcripts of audio-recorded behavioural support session sessions delivered by a national telephone quit-line service. It was possible also to reliably apply the BCT taxonomy to assess fidelity, therefore highlighting the further utility of the taxonomy as method for monitoring the delivery of smoking cessation behavioural support interventions in clinical practice. In both studies, fidelity of delivery was found to be low, with on average 66% and 41% of manual-specified content delivered by face-to-face and telephone services respectively. Extent of fidelity varied according to session type, duration, practitioner, and individual BCT in both settings. These findings are consistent with those from systematic reviews and individual trials examining the fidelity of delivery of behaviour change interventions in other domains (Bellg et al., 2004; Borrelli, 2011; Borrelli et al., 2005; Caldwell et al., 2012; Collins et al., 2009; Dane & Schneider, 1998; Dewing et al., 2013; Dusenbury et al., 2003; Hardeman et al., 2008; Hatch-Maillette et al., 2013; Moncher &

Prinz, 1991; Santacroce et al., 2004), and therefore add to an increasing body of evidence demonstrating the inconsistency and variability with which complex behaviour change interventions are actually delivered.

Quality of intervention delivery was addressed by Study 6 (Objective 2c), which aimed to establish and pilot a method for reliably assessing the quality with which a key intervention component, goal-setting, was delivered in practice. The key components of comprehensive and appropriate goal-setting (e.g. set a clear quit date, within an appropriate time frame), were identified from four national guidance documents. These formed the content of a 10-point rating scale, the Quality of Goal-Setting Rating Scale (QGRS), to score quality of goal-setting in practice. The QGRS was applied to code transcripts of 85 pre-quit behavioural support sessions delivered by a national telephone quit-line service. Inter-rater reliability for the QGRS was high, thus demonstrating its utility as a quality assessment approach. The average quality with which Stop Smoking Practitioners facilitated the process of setting a quit date with the client was found to be low. Furthermore, Study 6 (Objective 3) was also an exploratory study that aimed to investigate whether quality of goal-setting in practice was significantly associated with likelihood of clients enacting a quit attempt as planned. In the same sample of 85 pre-quit sessions, it was found that only a very small number of clients (21%) who set a quit date during sessions with a Stop Smoking Practitioner actually went onto enact their quit attempt as planned. This finding represents an intention-behaviour gap, and is consistent with the wider literature demonstrating that the intention to change behaviour does not always result in actual behaviour change (Gollwitzer et al., 2009; Sheeran, 2002; Sheeran et al., 2005; Webb & Sheeran, 2008). However, it was found that higher quality of goal-setting in the pre-quit session was significantly associated with an increased likelihood of clients making a quit attempt as planned, particularly

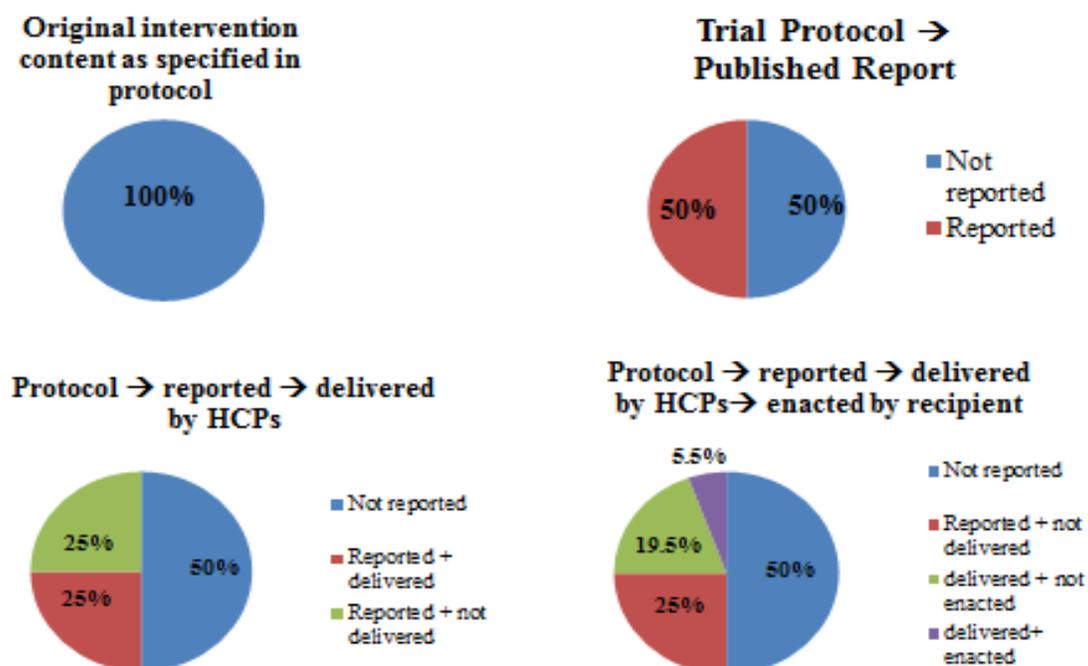
if a clear quit date was set with the client (i.e. specific dd/mm/yy as opposed to ‘in two weeks’ time’). This finding is consistent with those from systematic reviews demonstrating that better implementation of interventions is associated with improved outcomes (Dane & Schneider, 1998; Durlak & DuPre, 2008), and from studies showing an association between delivery of goal-setting and improved outcomes (Hankonen et al., 2013). Also, the finding that a single component of goal-setting was independently associated with improved outcomes demonstrates how the content of complex behaviour change interventions may be deconstructed to identify which particular components are contributing to effective outcomes (i.e. the ‘active ingredients’).

8.2. Examining the translation of evidence into practice for smoking cessation behavioural support

It is possible to collectively examine findings from Studies 1-6 to investigate whether and how effective interventions are translated from research into practice (Grant, Mayo-Wilson, Melendez-Torres, & Montgomery, 2013). For example, Study 2 found that on average, less than half of the BCTs included in the description of smoking cessation behavioural support interventions in trial protocols are subsequently also reported in the trial’s published report (Lorenatto, West, Stavri, et al., 2013). One could start with the assumption that the content (i.e. BCTs) described in the trial protocol represents 100% of the content of the original intervention that was developed, delivered in trial settings, evaluated and found to be effective (i.e. evidence-based); although it is recognised that this is unlikely to be the case as fidelity to protocol has been shown to be low in trial settings as well (Borrelli, 2011). Given the findings from Study 2, only 50% of this original content will be disseminated through published reports (Figure 13). This finding represents a translational gap in the early stages of the implementation process, and an immediate ‘loss’ of 50% of the original intervention. This translational gap has implications

for policy makers, guideline developers, service managers and commissioners as these are likely to obtain evidence from published reports as to what is and is not effective in supporting smokers to successfully quit (Rosenfeld et al., 2013). In line with an evidence-based healthcare approach, this evidence will then inform the content of clinical guidelines, treatment manuals, and healthcare professional training, which collectively will in turn influence delivered clinical practice (Davidson et al., 2003; Rosenfeld et al., 2013). However, as shown in Study 2, published reports are currently incomplete and do not provide comprehensive descriptions of all the components comprising the intervention found to be effective. Therefore, any guidelines, training or manuals based on the content of these published reports will consequently also be ‘incomplete,’ and potentially only contain recommendations regarding 50% of the original evidence-based intervention.

Figure 13: The translation of evidence into practice for smoking cessation behavioural support interventions



Findings from Studies 4 and 5 highlight a second translational gap when interventions are actually delivered in clinical practice. In both face-to-face and telephone-based behavioural support intervention sessions, on average, less than 50% of the ‘recommended’ or ‘intended’ format and content of behavioural support sessions specified in the service treatment manuals was actually delivered by Stop Smoking Practitioners in clinical practice (Lorenatto, West, Christopherson, & Michie, 2013). If one considers this additional translational issue cumulatively with previous ‘loss’ at the evidence dissemination stage, only an estimated 25% of the original evidence-based intervention is therefore actually being delivered to smokers at the clinical practice stage.

Furthermore, findings from Study 6 demonstrate that this small proportion of original intervention content that is being delivered is not typically being delivered with quality – ‘appropriately’ and ‘comprehensively,’ by Stop Smoking Practitioners; underlining a third translational gap. Only a small proportion of intervention recipients enacted the target behaviour change (21%), which represents a fourth translational gap. It may therefore be estimated on the basis of these findings that, cumulatively, approximately only 5.5% of the originally developed evidence-based intervention is being disseminated, delivered and enacted by recipients to achieve the target behaviour change (Figure 13). There is thus an estimated loss of 94.5% throughout the process of translating evidence-based smoking cessation behavioural support interventions into intended outcome.

Some ‘loss’ or ‘waste’ in the production, reporting, and implementation of research evidence is inevitable, and to a degree tolerable (Chalmers & Glasziou, 2009). However, based on the present findings, the cumulative waste in the translation of evidence-based smoking cessation behavioural support interventions into clinical practice is substantial. If the losses estimated on the basis of the findings from the studies in this thesis are reflective of behavioural support more generally (i.e. delivered in other NHS Stop Smoking Services or behavioural support in other contexts), then the substantial financial and resource investment made into developing, evaluating, disseminating and implementing these interventions is unlikely to achieve the goal of promoting smoking cessation, or the resulting end-goal of reducing smoking prevalence and associated mortality and morbidity.

8.3. Implications for research, policy and practice.

These identified translational gaps hold numerous implications for future research and improving policy, guideline development and clinical practice. As gaps were observed at different stages in the translation of evidence into practice, there is no single solution to improving the implementation of smoking cessation behavioural support. There are several key groups necessary for the effective translation of evidence into practice, including: researchers involved in developing and evaluating interventions, and disseminating evidence; policy makers, guideline developers, service managers and commissioners responsible for establishing recommended or intended practice; healthcare professionals responsible for delivering interventions; and intervention recipients.

8.3.1. Minimising the translational gap at the evidence dissemination stage

The first translational gap was observed at the stage of disseminating evidence, specifically, in researchers' tendency to under-report intervention content, as specified in trial protocols, in published trial reports (Study 2) (Lorenatto, West, Stavri, et al., 2013). The content of complex interventions is often reported in inadequate detail, using variable terminology (Michie, Abraham, et al., 2011). This has implications for policy makers and guideline developers, as poor specification hampers the usability of these published reports for establishing what constitutes best practice (Rosenfeld et al., 2013). Therefore to promote the uptake of findings and make disseminated evidence more usable, it is necessary to improve the specification of interventions to ensure an adequate level of detail that enables faithful replication (Michie, Abraham, et al., 2011). The recent development of taxonomies of BCTs provides a common language and tools for achieving this (Abraham et al., 2011; Abraham & Michie, 2008; Michie, Ashford, et al., 2011; Michie, Hyder, et al., 2011; Michie et al., 2013; Michie et al., 2012). Study

1 demonstrated how the taxonomy of smoking cessation BCTs could be applied to shed some light on the ‘black box’ that is the content of evidence-based behavioural support interventions for pregnant smokers, by enabling the reliable identification and characterisation of BCTs comprising these effective interventions (Lorencatto et al., 2012). It was demonstrated in Study 3 that inexperienced coders could be trained to apply this taxonomy of smoking cessation BCTs to reliably specify components of behaviour change interventions as delivered in practice (Lorencatto, West, Seymour, & Michie, 2013). Similarly, a recently developed program for training new coders to apply a cross-behavioural domain taxonomy of 93 BCTs (Michie et al., 2013) to specify the components of behaviour change interventions has also been shown to be effective in improving coding reliability (Johnston et al., 2013). Training researchers is one means of improving the specification and usability of reported intervention content. Work is underway to evaluate the extent to which the cross-domain BCT taxonomy (Michie et al., 2013) may be reliably used by researchers to improve the writing of descriptions of behaviour change interventions, and whether it is perceived as an acceptable tool for doing so (Wood et al., In preparation). Using the taxonomy when preparing descriptions of intervention content will help ensure that intervention content is more precisely specified using consistent terminology from the offset.

Precisely specified intervention descriptions also need to be readily accessible in full, unbiased and usable published peer-reviewed reports if they are to be accessed by policy makers, guideline developers, and service managers and commissioners (Chalmers & Glasziou, 2009). There is evidence from systematic reviews that the use of guidelines such as CONSORT (Altman et al., 2001; Moher et al., 2001) improves the quality of published intervention reports (Plint et al., 2006). Authors preparing published reports therefore need to be made more aware of and

trained to use reporting guidelines and standards, as findings from Study 2 indicate that reporting practices do not appear to be improving over time (Lorenatto, West, Stavri, et al., 2013). Furthermore, the current peer-review process focusses primarily on evaluating whether the study report is innovative and contributes to the knowledge base, with less emphasis placed on evaluating the usability of the prepared report. Peer-review needs to also include a consideration of how adequate the report is in terms of its specificity and potential for supporting subsequent replications or evidence synthesis (Chalmers & Glasziou, 2009).

Study 2 demonstrated the difficulty of accessing further detail or information on interventions, such as by obtaining trial protocols from authors (Lorenatto, West, Stavri, et al., 2013). Reasons for not publishing detailed intervention descriptions have included word count and space considerations (Chalmers & Glasziou, 2009). However, with the advent of facilities for publishing supplementary materials online, this is no longer a viable excuse. Journal editors should encourage, or even require, all authors to publish a trial protocol prior to publishing the evaluative report, or to make protocols available electronically as supplementary materials. Such a policy is already active in some journals such as *Addiction* or *Implementation Science* (Michie & Abraham, 2008; West, 2008), but needs to be adopted more widely to help increase access to detailed information on intervention content. Authors need to be made more aware of these supplementary publishing facilities, and the publication of supplementary materials should be clearly indexed on the published report to also increase awareness of these materials to those reading the report.

Together, these strategies are likely to reduce the translational gap and associated information loss at the evidence dissemination stage by ensuring access to more complete and well-specified intervention descriptions. Policy makers, guideline developers, service commissioners and

managers will be able to establish ‘best practice’ and ‘professional standards’ on published descriptions that are more representative of the original intervention content evaluated as effective. This in turn will help bridge research and practice, by encouraging the more complete translation of evidence into practice.

8.3.1. Minimising the translational gap at the stage of healthcare professionals delivering behaviour change interventions in practice

The second translational gap was observed at the point of delivering interventions in clinical practice (Studies 3-6) (Lorenatto, West, Christopherson, et al., 2013; Lorenatto, West, Seymour, et al., 2013). In order to translate clinical guidelines and manuals into practice, it is necessary for evidence-based interventions to be delivered fully (i.e. with fidelity) and well (i.e. with quality) by healthcare professionals (Santacroce et al., 2004). However, Stop Smoking Practitioners did not consistently deliver manual-specified intervention content with fidelity and quality (Studies 4-6). This finding holds implications for improving clinical practice; future research needs to consider how best to change the behaviour of Stop Smoking Practitioners to improve the fidelity and quality with which healthcare is delivered in clinical practice.

One approach to improving clinical practice is through training. It was possible to identify the particular types of sessions, individual practitioners and BCTs for which fidelity was lowest (Studies 4 and 5); these findings represent specific training needs, and should form the basis for developing future practitioner training or continuing professional development programs. Furthermore, eleven evidence-based BCTs for delivering specialist pregnancy behavioural support interventions were identified (Study 1), and the quality of delivery of a key BCT, goal-setting, was shown to be associated with improved intervention outcomes (Study 6). In order to ensure stop smoking practitioners are equipped with the evidence-based knowledge and skills

(i.e. competences) for delivering effective behavioural support, these findings should also inform training and the establishment of professional standards.

Indeed, evidence will not improve clinical practice unless healthcare providers adopt evidence in practice (Eccles et al., 2007). It has been argued that to improve the translation of new research knowledge (i.e. evidence) into clinical practice, it is necessary to embed knowledge translation into healthcare systems (Grimshaw et al., 2004). A common knowledge translation activity is continuing professional training, education and development. It is therefore necessary to engage the providers of continuing professional training, education and development programs in the evidence translation process. An emerging model of how to embed a knowledge translation program into a healthcare system guidance development programme is the multidisciplinary ‘Translation Research in a Dental Setting’ (TRIADS) research collaboration (Clarkson et al., 2010). The research conducted as part of TRIADS is integrated into the target healthcare system and is directly relevant to the healthcare system’s priorities. There is clear engagement with those responsible for translating evidence through a shared generation of knowledge between the guidance development team, educational delivery teams, and interdisciplinary knowledge translation research team (Clarkson et al., 2010). As well as providing an evidence-based knowledge and skills training and certification program for NHS Stop Smoking Practitioners, the National Centre for Smoking Cessation and Training (NCSCT) also conducts research into improving the delivery of smoking cessation behavioural support interventions in clinical practice (www.ncsct.co.uk)(Brose, West, et al., 2012). Therefore, organizations such as the NCSCT hold an important role in the process of translating new evidence regarding smoking cessation behavioural support into practice via its professional continuing education, training and development activities. The identification of training new needs and evidence (i.e. evidence-

based BCTs) (Studies 1, 4-6), should therefore also inform updates to the NCSCT's knowledge and skills training programs.

A second approach to improving clinical practice is to consider 'how' policy makers, guideline developers, service managers and commissions specify recommended content to healthcare professionals. Findings from Studies 4 and 5 raised the question of the extent to which Stop Smoking Services' treatment manuals are fit for purpose (Lorencatto, West, Christopherson, et al., 2013). As with the content of published reports, in order to facilitate healthcare professionals to act on evidence-based guidelines or recommendations in treatment manuals, the content of these documents needs to also be clearly specified in a manner that will be accessible and usable to those tasked with delivering this content. There is evidence that the wording of a behavioural instruction can influence the likelihood that it will be acted on by affecting comprehension, recall, planning and behaviour (Ley, 1998; Michie & Johnston, 2004). A review of the attributes of ten national clinical guidelines found that general practitioners were more likely to follow guidelines that were concrete and precise (68%) rather than vague or non-specific (36%) (Grol et al., 1998). Future research needs to consider the specificity of behavioural instructions in smoking cessation behavioural support treatment manuals and clinical guidelines. Those individuals involved in developing treatment manuals and clinical guidelines need to ensure recommendations are precisely specified in behavioural terms, that is, *what* needs to be done, by *whom*, *when*, *where* and *how*, in order to increase the likelihood of Stop Smoking Practitioners delivering these behavioural instructions in clinical practice (Michie & Johnston, 2004).

An associated question that also requires consideration is 'what' Stop Smoking Practitioners are being asked to deliver by clinical guidelines and treatment manuals. Better implementation, that is, higher fidelity and quality of intervention delivery, has demonstrated associations with

improved outcomes (Durlak & DuPre, 2008). However, it is unclear *what* optimal level of fidelity and quality of delivery is required to achieve these improved outcomes. The ‘more is better’ rationale for requiring 100% fidelity has been questioned (Leventhal & Friedman, 2004). In Studies 4 and 5, the treatment manuals from the Stop Smoking Services examined were found to be extremely comprehensive in terms of the number of BCTs practitioners were expected to deliver within each session (e.g. up to 28 BCTs per session in the telephone quit-line service). Sessions were found to last on average just 13 minutes; meaning that practitioners would need to deliver on average 2 BCTs per minutes to achieve 100% fidelity. Whether in this context 100% fidelity represents an expectation that is feasible, relevant, or in fact beneficial in practice is questionable. Intervention providers may work better if a specified degree of flexibility or adaptation to the local context is allowed for (Craig et al., 2008). Expectations regarding fidelity and quality of delivery will vary depending on the nature of the behaviour change intervention being implemented. For instance, the widely implemented Expert Patient Programme for self-management of chronic illness is intended to be delivered with strict adherence to the content and format of a regularly updated ‘tutor’ manual (Lorig et al., 1999). In contrast, the handbook for the also widely implemented NHS Health Trainers intervention was specifically developed to be applied flexibly. The handbook provided information and explanations about psychological techniques and theories of behaviour change, alongside practical suggestions of how to use these techniques. However, as lay Health Trainers worked in a wide range of settings and with individuals of varying health needs, the handbook was intended to be used flexibly and adapted to local context (Michie et al., 2008).

Policy makers, guideline developers, service managers and commissioners may wish to consider this more flexible approach to fidelity of delivery, as it may be more appropriate for smoking

cessation behavioural support interventions given that NHS Stop Smoking Services have been widely implemented across England and are also delivered in diverse settings to a wide range of individuals (Bauld et al., 2010). Reducing the number of BCTs that Stop Smoking Practitioners are expected to deliver with 100% fidelity and quality may increase the likelihood of recommendations being adhered to in practice. Proponents of a more flexible approach to fidelity argue that 100% fidelity should only be expected for those intervention components that are evidence-based, unique, and essential to the intervention (Collins et al., 2009; Waltz et al., 1993). Given the complex, multi-faceted nature of smoking cessation behavioural support, it may not always be clear what the individual components of interventions are, let alone those that are unique, essential or evidence-based. Evidence of effectiveness has only been established for a limited number of smoking cessation BCTs from the taxonomy (Study 1 and 6) (Lorençatto et al., 2012; Michie, Churchill, et al., 2011; West et al., 2011; West, Walia, et al., 2010). Manuals could focus on recommending strict fidelity for these BCTs with an established evidence-base, and allow for flexibility in the delivery of those recommended BCTs for which individual effectiveness has not yet been demonstrated. Treatment manuals will need to be revised accordingly as future research produces new evidence for the effectiveness of additional BCTs.

In translational research, it is also necessary to consider ‘what’ is expected to be delivered by intervention providers earlier on in the implementation process. The MRC framework for developing and evaluating complex interventions argues that it is important for researchers to consider implementation at the very beginning, when developing interventions (Craig et al., 2008). Often the aim when developing behaviour change interventions is to identify the ‘treatment package’ of components (i.e. BCTs) that maximises the likelihood of outcomes being achieved. However, the entire treatment package may not always be necessary to achieve

outcomes, or always feasible to deliver in practice with available resources (i.e. time); as evidence by the telephone quit-line in Study 5. The multi-phase optimisation strategy (i.e. MOST) is a recently developed engineering-inspired framework for optimising the development and evaluation of complex, multi-component behavioural interventions (Collins, Murphy, & Strecher, 2007). MOST emphasizes a ‘resource management principle,’ that is, efficiency and careful management of resources throughout the intervention development process. Prior to conducting an evaluative RCT of a selected ‘treatment package,’ MOST advocates that researchers should have a clearly specified set of research questions and be aware of what resources are available and required of the intervention in target settings. Potential intervention components should be carefully screened for inclusion and selected on the basis of theoretical rationale, empirical evidence and clinical experience, whilst also maintaining a consideration of constraints such as what will subsequently be feasible to deliver given limitations in time, financial and practical resources (e.g. number of providers).

Following MOST, implementation is considered from the offset for interventions in the domain of translational research. The aim is not to identify the single ‘best’ combination of components that maximises the likelihood of optimal outcomes being achieved in the trial setting. Rather, the aim is to identify an optimal, ‘good enough,’ combination of components (i.e. ‘treatment package’) that on balance increases both the likelihood of outcomes being achieved widely in target settings (i.e. across a greater number of services) and advances scientific knowledge given potential resource constraints (Collins et al., 2007). Future research is needed to identify the balanced, ‘optimized,’ treatment package of BCTs for smoking cessation behavioural support interventions that will promote positive quit outcomes within the constraints of clinical practice; for example, an optimal package of effective BCTs that can be feasibly delivered within the

limited session duration of the telephone quit-line. The development of future smoking cessation behavioural support interventions by researchers would therefore benefit from using the MOST approach to help ensure implementation and resource constraints are considered early in the development process. Using these feasible, optimized, interventions as a basis for the content of clinical guidelines and treatment manuals may in turn promote higher fidelity of delivery of manual-specified content.

A third approach to improving clinical practice and addressing the translational gap resulting from low fidelity and quality of intervention delivery is to use findings from Studies 4-6 to develop interventions aiming to directly change healthcare professional behaviour. Implementation research has played a central role in developing interventions that are designed to change the clinical practice behaviour of healthcare professionals (French et al., 2012; Grimshaw et al., 2004). A range of implementation intervention strategies have been developed and evaluated to date, including: continuing medical education, dissemination and implementation of guidelines, printed educational materials, outreach visits, opinion leaders, audit and feedback, reminders and computerized decision support, mass media and continuing quality improvement (Bero et al., 1998; Grimshaw et al., 2001; Grimshaw et al., 2004). It is unclear which specific strategy is most effective in improving implementation, and the effectiveness of different strategies is likely to be sensitive to context (Davies, Walker, & Grimshaw, 2010; Grimshaw et al., 2001; Grimshaw et al., 2004). It is generally found that passive strategies (i.e. dissemination, printed educational materials) are ineffective and that multi-faceted interventions targeting different barriers to change are more likely to be effective than single interventions (Grimshaw et al., 2001). It is also unclear how these strategies work as a review of the use of theory in 235 evaluations of guideline dissemination and implementation

strategies found that a theoretical rationale was only explicitly mentioned in a minority of studies (Davies et al., 2010). Health psychology proposes several theories that aim to predict, explain or achieve health related behaviour change (Ogden, 2012). As clinical practice is a form of human behaviour, it is important also to ensure implementation interventions are developed with an explicit, underlying theoretical rationale (Foy, Francis, et al., 2007; Penney & Foy, 2007).

Indeed, implementation interventions to change the clinical behaviour of stop smoking practitioners would also benefit from following a systematic, theory-based approach because this provides a generalizable framework through which to understand factors influencing health professional behaviour (Foy et al., 2005; French et al., 2012). To change behaviour, it is first necessary to precisely specify what specific behaviours are being targeted for change (Dumbrowski et al., 2012; Kolehmainen & Francis, 2012). The findings from studies 4-6 in this thesis identified particular aspects of the delivery of smoking cessation behavioural support interventions that require improvement. For example, in Study 4 Stop Smoking Practitioners delivered the evidence-based BCT ‘advise on the use of social support’ in only 15% of occasions recommended by the manual. In Study 6, failure to set a clear quit date with the client significantly decreased the likelihood of clients enacting a quit attempt as planned. These problematic aspects of service delivery could serve as behavioural targets for future interventions to change the clinical practice behaviour of Stop Smoking Practitioners. For instance, these findings could be fed back to practitioners as part of a theory-based audit and feedback implementation intervention.

Audit and feedback is defined as a summary of clinical performance of healthcare over a specified period of time, which is provided to healthcare professionals with data on performance and is widely used as a strategy to improve quality of care in many healthcare systems (Ivers et

al., 2012). A Cochrane review of audit and feedback interventions demonstrated evidence of small to medium effects of audit and feedback strategies on improving clinical practice and patient outcomes (Ivers et al., 2012; Jamtvedt, Young, Kristoffersen, O'Brien, & Oxman, 2006). However, as with implementation interventions more generally, the effect of audit and feedback strategies is variable (Ivers et al., 2012). Larger effects were observed if baseline compliance by healthcare professionals was low, if the source of feedback was a supervisor or colleague, if feedback was provided over multiple occasions, in both written and verbal formats, and included both explicit targets for behaviour change and an action plan (Ivers et al., 2012).

To develop effective audit and feedback interventions it is necessary to understand how and when this intervention strategy works best (Foy et al., 2005); theory may contribute this understanding. For example, many of the component BCTs involved in the process of delivering audit and feedback, such as 'providing feedback on performance,' 'goal-setting,' 'action-planning,' and 'reviewing set goals' can be linked to Control Theory (Carver & Scheier, 1982) in that individuals manage their behaviour by knowing what they want to achieve (i.e. goal/standard), trying to achieve this (i.e. action), assessing whether progress has been achieved (i.e. providing feedback on performance/review set goals), and adapting behaviour as a result of feedback (i.e. action planning) (Gardner et al., 2010; Ivers et al., 2012). The finding that audit and feedback strategies are more effective when feedback provides explicit targets for behaviour change (i.e. goals) and is accompanied by action plans is congruent with Control Theory (Ivers et al., 2012). Future audit and feedback interventions to improve the delivery of smoking cessation behavioural support interventions could be developed on this basis. The findings from Studies 4, 5, and 6 in this thesis provide information for the clinical 'audit' component, and represent explicit targets for behaviour change (i.e. goals) among Stop Smoking Practitioners. In line with

Control Theory, the feedback component should include precisely specified action plans (i.e. who/where/when) as to how to change these behavioural targets (e.g. who/when/where the BCT ‘advise on use of social support’ should be delivered in practice).

Findings from Studies 4 and 5 provide evidence of Stop Smoking Practitioner’s variable use of treatment manuals when delivering behavioural support, as fidelity of delivery for manual-specified content was low. Therefore, a second potential implementation intervention to improve clinical practice could be aimed at enhancing fidelity to treatment manuals. There is evidence from the psychotherapy literature that therapists’ reported use of treatment manuals when treating eating disorders using cognitive behavioural therapy is variable, and that manual use varies according to professional characteristics (i.e. years of experience, educational level) (Tobin, Banker, Weisberg, & Bowers, 2007; Wallace & von Ranson, 2011). However, what factors influence manual use amongst Stop Smoking Practitioners is unclear. There is preliminary evidence from a national survey of Stop Smoking Practitioners working in the NHS Stop Smoking Services that practitioners with more favourable attitudes regarding the perceived usefulness of treatment manuals are more likely to use manuals and achieve higher successful quit rates (Lorenatto, Michie, McEwen, West & Brose, In preparation). ‘Attitudes’ comprise a central component of behaviour change theories such as the Theory of Planned Behaviour (TPB) (Ajzen, 2002). Other components in the TPB include ‘subjective norms,’ and ‘perceived behavioural control;’ it is possible that the attitudes and use of manuals by other practitioners within the same service influence an individual practitioner’s use of manuals (i.e. subjective norms), or that the practitioner’s perceived self-efficacy for competently delivering manual-specified content (i.e. perceived behavioural control) also influences manual use. Therefore, future research is needed to apply theories, such as the TPB, to identify barriers and facilitators

to manual use amongst Stop Smoking Practitioners. These findings could in turn provide a basis for informing the development of future implementation interventions that aim to improve Stop Smoking Practitioners' fidelity to treatment manuals. Such an approach has been used to develop theory-based implementation interventions in other clinical behaviour domains, including: compliance with diagnostic imaging guidelines for spine disorders (Bussieres et al., 2012), blood transfusion (Francis, Stockton, et al., 2009; Francis, Tinmouth, et al., 2009), prescribing of antibiotics (Eccles et al., 2007), management of lower back pain (Grimshaw et al., 2011) and appropriate disclosure of diagnosis of dementia (Eccles, Francis, et al., 2009; Foy, Bamford, et al., 2007; Foy, Francis, et al., 2007).

8.2.3. Minimising the translational gap at the intervention recipient enactment stage

The final stage in the implementation process, 'enactment' involves intervention recipients' actual performance of the intervention cognitive and behavioural skills in the intended situations at the appropriate time (in this case making a quit attempt as planned on the agreed quit date) (Bellg et al., 2004; Borrelli, 2011). In Study 6 the final translational gap was observed at this stage, whereby the majority (79%) of smokers examined failed to enact their quit attempt as planned, despite being delivered an evidence-based BCT to encourage this (i.e. facilitate goal-setting). It is hoped that by optimising the initial specification of interventions during their development, the subsequent dissemination of evidence, and the fidelity and quality with which interventions are delivered, the translational gaps observed in the earlier stages of the implementation process will be reduced, and that smokers will therefore receive a greater amount of the 'original' evidence-based intervention (i.e. less information loss). This in turn may increase the likelihood of intervention recipients enacting the desired behaviour change and achieving target outcomes. Nonetheless, intervention strategies to increase the enactment of

BCTs delivered to smokers as part of the behavioural support intervention may still be required. Recommendations from the National Institute for Health Behaviour Change Consortium regarding strategies to improve enactment include: first assessing intervention receipt/understanding using questionnaires or interviews, encouraging self-monitoring, checklists/reminders, and maintaining longitudinal contact in between or after intervention sessions (i.e. follow up telephone calls/mailed information) (Bellg et al. 2004). Some of these enactment enhancing strategies are reflected in existing BCTs from the smoking cessation taxonomy; for example ‘Encourage self-monitoring,’ ‘Check client’s understanding and confirm client decisions,’ and ‘Give options for additional and/or later support (i.e. follow-up telephone calls)’ (Michie, Hyder, et al., 2011). Behavioural support services in clinical practice, such as the NHS Stop Smoking Services, may therefore wish to include these BCTs as part of their treatment manuals in order to maximise the likelihood of clients enacting smoking cessation behaviour change strategies.

8.4. Conclusions

As with behaviour change interventions more generally, the implementation of effective smoking cessation behavioural support interventions in clinical practice is a slow and inconsistent process (Eccles, Armstrong, et al., 2009). There is substantial information loss and gaps in the process of translating evidence-based smoking cessation behavioural support interventions into clinical practice. These gaps hold numerous implications for future research and for improving policy, guideline development, and clinical practice. Improving the uptake of evidence into practice will require behaviour change by several groups of individuals- from researchers, to guideline developers, stop smoking service managers, commissioners, clinicians, and smokers themselves. The findings from this thesis contribute to our understanding of how smoking cessation behavioural support interventions are implemented and how this relates to outcome. They also support the identification of specific training needs and behavioural targets for future implementation interventions, which should be developed systematically with a clear theoretical rationale. Given the findings that implementation of smoking cessation behavioural support interventions is variable and associated with quit outcomes, it is necessary to ensure that routine strategies for monitoring the implementation of behavioural support interventions are established wherever such interventions are being delivered as part of wider clinical practice (e.g. the NHS Stop Smoking Services). The taxonomy of smoking cessation BCTs (Michie, Hyder, et al. 2011) served as a reliable method for examining different aspects of the translation of evidence into practice; it enabled the precise specification of effective behavioural support interventions, the assessment of current reporting practices, and also of the fidelity and quality of intervention delivery in practice. Taxonomies of BCTs have been developed for other health behaviours, including physical activity (Michie, Ashford, et al., 2011), alcohol use (Michie et al., 2012), safe

sex (Abraham et al., 2011), and a cross-domain BCT taxonomy has recently also been developed (Michie et al., 2013). The extent to which these taxonomies may also be applied to systematically examine factors related to the translation of evidence into practice for behaviour change interventions in these other domains has yet to be examined. Implementation research is still at an early stage of development (Eccles, Armstrong, et al., 2009). Even modest efforts to understand and improve the translation of evidence into practice are likely to yield substantially increased benefits for population health (Moher et al., 2001).

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APPENDICES

Appendix 1: Coding framework developed to specify BCTs in transcripts of audio-recorded behavioural support sessions.



V 1.00 Oct-26-2010

Specifying behavioural support for smoking cessation in practice
Coding frame for transcripts and protocols

Name of Coder	
Date of Coding	day/ month/ year _____ / _____ / _____
Service ID	S_____
Practitioner ID code	P_____
Client ID code	C_____
Transcript file number	
Time taken to code the transcript/ protocol	_____ hrs _____ mins

BCT CODE ¹	BCT LABEL ²	BCT DESCRIPTION ³	EXAMPLE OF BCT USE ⁴	SCORE ⁵ 0= Not Used 1= Used	LINE / PAGE No.(transcript) ⁶	EXAMPLE QUOTES ⁷	FREQUENCY ⁸ (total No. Citations in session)
<i>Specific focus on behaviour (B) and addressing motivation (M)</i>							
BM1	Provide information on the health consequences of smoking and smoking cessation	Give, or make more salient, information about the physical/health harms caused by smoking and the benefits of stopping; distinguish between the harms from smoking and nicotine; debunk myths about low tar and own-roll cigarettes.	'now CO is a poisonous gas contained in the smoke that you inhale from cigarettes and it replaces some of the oxygen in your blood and contributes towards coronary heart disease'				
BM2	Boost motivation and self-efficacy	Give encouragement and bolster confidence in ability to stop. Can include telling the person that they can successfully stop smoking, arguing against self-doubts and asserting that they can and will succeed.	'That's brilliant-well done! you know it's amazing really given all those things that you've managed not to smoke, that really is all power to you for doing that'				
BM3	Provide feedback on current behaviour and progress	Give feedback arising from assessment of current self-reported or objectively monitored behaviour (e.g. expired-air CO) and/or progress towards becoming a permanent non-smoker.	'so you've done lots of things right and this next week is about building on the success of the first week'				
BM4	Provide rewards contingent on not smoking	Give praise or rewards if the person has not smoked.	'Well I'm going to give you some congratulations first of all even though you've been feeling down this week - Well done for not				

			smoking, that's three weeks without a cigarette'				
BM5	Provide normative information about others' behaviour and experiences	Involves providing information about how the smoker's experience compares with that of other smokers who are trying to quit, as to indicate that a particular behaviour or sequence of behaviours are common, or uncommon, amongst other smokers trying to quit.	'well it's very common, around about a third of people who take champix do experience mild to moderate nausea...but many people decide that it's worth putting up with, but there're a few things that you can perhaps do that others have found useful'				
BM6	Prompt commitment from the client there and then	Encourage the smoker to affirm or reaffirm a strong commitment to start, continue or restart the quit attempt.	'so having explained the reasons for not even a puff after your quit date, what I would really like to hear you say now, rather than me say it, is that you're prepared to make every effort to not even have one puff on a cigarette after your quit date, can you do that?'				
BM7	Provide rewards contingent on effort or progress	Give praise or other rewards for the effort the smoker is making in relation to smoking cessation and if the smoker has engaged in	'none at all? That's amazing congratulations! You must feel great?'				

		activities that aid cessation, such as correct medication use.					
BM8	Strengthen ex-smoker identity	Explain the importance of regarding smoking that is 'not an option,' including the 'not a puff' rule, and construct a new identity as someone who 'used to smoke'	'you are committed to not having a cigarette, not even a puff, after today, whatever life throws at you'				
BM9	Facilitate identification of reasons for wanting and not wanting to stop smoking	Help the smoker to arrive at a clear understanding of his or her feelings about stopping smoking, why it is important to stop and any conflicting motivations.	'so what is it that made you want to stop smoking and made you want to stop now'				
BM10	Explain the importance of abrupt cessation	Explain why it is better to stop abruptly rather than cut down gradually if at all possible.	'the only really effective way of stopping smoking is not to remind your body or your mind at all about the effects of getting nicotine from cigarettes. So the best advice is to pick your quit date and stop completely'				
BM11	Measure CO and explain the purposes of CO monitoring	Measure expired- air carbon monoxide concentration and explain to the smoker the reasons for measuring CO at different time points (e.g. before and after the quit date)					
BM12	Conduct motivational interviewing	Adopt a formal motivational interviewing protocol					
<i>Specific focus on behaviour (B) and maximizing self-regulatory capacity/skills (S)</i>							
BS1	Facilitate barrier identification and problem	Help the smoker identify general barriers that might make it harder to stay off cigarettes (e.g. susceptibility	'Have you identified which cigarettes that you think you are going to miss the				

	solving	to cigarettes). Help the smoker develop general ways of addressing and overcoming these, and increasing facilitators (e.g. by generating alternative courses of action and pros and cons of each and weighing them up)	most? What do you think you can do at those times that might make it a little bit easier for you?				
BS2	Facilitate relapse prevention and coping	Help the smoker understand how lapses occur and how they lead to relapse. Plan how to maintain behaviour that has changed, by helping identify in advance situations in which the changed behaviour may not be maintained, and develop specific strategies for preventing lapses or avoiding lapses turning into relapse.					
BS3	Facilitate action planning/ develop a treatment plan	Work with the smoker to encourage generation of a clear, detailed quit plan including preparations for the quit attempt (e.g. obtaining medication).					
BS4	Facilitate goal setting	Help the smoker set a quit date and goals that support the aim of remaining abstinent	‘one thing that is really important for us to do today is agree a day that will actually be your quit date, so that will be the day from which you won’t be smoking at all, not even a puff’				
BS5	Prompt review of set goals	Review how far the smoker has achieved the main goal of abstinence and any other	‘so lizzie, great to see you back, I’m really keen to find				

		goals that are supportive of it (e.g. putting in place plans to avoid triggers). In most cases this will follow previous goal setting and an attempt to act on those goals, followed by a version of revision or readjustment of goals and/or means to attain them.	out how you've been doing- can I first of all can I ask how you've got on this week?''				
BS6	Prompt self-recording	Help the smoker establish a routine of recording potentially useful information (e.g. situations or times when urges are strong and less strong)					
BS7	Advise on changing routine	Advise on ways of changing daily or weekly routines to minimize exposure to smoking cues	'and if you carry on doing exactly the same things at the same times as you did when you were smoking (but doing them without a cigarette) it is going to make it even harder for you, it's really important that you plan to do something different at those times to make it a little bit easier for yourself'				
BS8	Advise on environmental restructuring	Advise on ways of changing the physical environment to minimize exposure to physical smoking cues (e.g. removing ashtrays from the house)	'go through all your coat pockets, drawers and your car to make sure there's no cigarettes in your house and also to get rid of any ash-trays or lighters as well'				

BS9	Set graded tasks	Set small achievable goals where appropriate (e.g. take one day at a time)					
BS10	Advise on conserving mental resources	Advise on ways of minimizing stress and other demands on mental resources (activities that require mental effort)	‘if you have a cigarette and those feelings go away and you start to think that smoking actually helps relieve stress but it’s really just relieving your withdrawal symptoms, but trust me, after your quit date you will learn to cope with stress without smoking and it will get better as long as you don’t smoke at all’				
BS11	Advise on avoiding social cues for smoking	Give specific advice on how to avoid being exposed to social cues for smoking (e.g. explaining to friends that you have stopped and asking them not to smoke around you)	‘it’s best if you can limit your exposure to cigarettes, especially in the first few weeks when it’s at its toughest and I think for people at work and with your husband at home, you don’t want to see them smoking because that’s going to make it a lot more difficult’				
BS12	Facilitate restructuring of social life	Advise on ways of changing social interactions so that they support rather than interfere with smoking cessation	‘I think for people at work and with your husband at home, you don’t want to see them smoking because that’s going				

			to make it a lot more difficult, you're probably going to have to make some changes to your social life as well to make it easier for yourself'				
BS13	Advise on methods of weight control	Advise on methods of weight control, including diet and/or exercise					
BS14	Teach relaxation techniques	Teach specific relaxation techniques and how and when to apply them					
<i>Promote adjuvant activities (A)</i>							
A1	Advise on stop smoking medication	Includes one or more of the following: - explaining the benefits of medication, safety, potential side-effects, contra-indications, how to use them most effectively, - advising on the most appropriate medication for the smoker - promoting effective use - explaining how to obtain medications, enacting the necessary procedures to ensure the smoker gets their medication easily and without charge where appropriate	'well medications as I've already mentioned can roughly double your chances of stopping smoking but they need to be used in a certain way and sometimes people need a bit of advice on that as well, but they're also not a magic bullet'				
A2	Advise on/facilitate use of social support	Advise on or facilitate development of social support from friends, relatives, colleagues or buddies.	'there're going to be times especially in the first couple of weeks after your quit				

			date when you're really going to need the help and support of friends and it is important that this is a quit attempt everyone knows about'				
A3	Ask about experiences of stop smoking medication that the smoker is currently using	Asses usage, side effects and benefits experienced of medication that the smoker is currently using.	'you've been taking champix for two weeks. Has there been anything in the past week that's causing you problems with the medication?'				
A4	Give options for additional and later support	Give information about options for additional support where these are available (e.g. websites, self-help groups, telephone helpline)					
General aspects of the interaction (R) focusing on communication (C)							
RC1	Build general rapport	Establish a positive, friendly and professional relationship with the smoker and foster a sense that the smoker's experiences are understood	'Hi Lizzie, my name's Angela, and it's great to see you here'				
RC2	General practitioner communication approaches	Communication that Includes one or more of the following: eliciting and answering questions, using reflective listening, summarizing information, and confirming client decisions	'can I just ask how you are feeling about your quit attempt and making it with the Stop Smoking Service?' 'so if I can just summarise what we've agreed today				

			and you can let me know whether I've got this correct or not'				
RC3	Emphasise choice	Emphasise client choice within bounds of evidence based practice					
RC4	Provide reassurance	Give general reassurance to the smoker that his/her experiences are normal and time limited, and provide positive expectations of success based on experience with other smokers in the same situation	'now seeing someone like myself who has been specially trained in smoking cessation will roughly double your chances of stopping smoking so you've definitely come to the right place'				
RC5	Tailor interactions appropriately	Use relevant information from the client to tailor the behavioural support provided					
RC6	Offer/direct towards appropriate written materials	Distinguish what are, and are not, appropriate written materials and offer/direct clients to these in ways that promote their effective use					
RC7	Information gathering and assessment	Any information gathering that provides the practitioner with the knowledge needed from the client for appropriate behaviour change techniques to be delivered. Includes one or more of the following: <ul style="list-style-type: none"> - Assessing current and past smoking behaviour - Assessing current readiness and ability to quit 	'can I just ask you a few questions about your smoking, at what age did you start?' 'I'm sure you know how difficult it is to stop smoking and you're going to need to be really motivated, how are you feeling about that?' 'can I just ask you				

		<ul style="list-style-type: none"> - Assessing past history of quit attempts - Assessing withdrawal symptoms - Assessing nicotine dependence - Assessing number of contacts who smoke - Assessing attitudes to smoking - Assessing level of social support - Assessing physiological and mental functioning 	<p>about any previous quit attempts that you might have made, have you made any serious quit attempts in the past?’</p> <p>‘It is important for us to know how dependant you are on cigarettes so if I can ask you a couple of questions, first of all how many cigarettes a day do you smoke’</p>				
RC8	Explain how tobacco dependence develops	Give an explanation of the development of tobacco dependence and the effect of nicotine	‘when people start smoking, their brain actually undergoes physical changes which means that people’s minds and bodies get used to regular doses of nicotine. what happens with smokers is that, if they haven’t smoked for a whole, as little as an hour and a half, then their body and their mind starts to miss the nicotine that they’re used to getting’				
RC9	Explain	Explain to the smoker the	‘...involves seeing				

	expectations regarding the treatment programme	treatment programme, what it involves, the active ingredients, and what it requires of the smoker	me weekly and that is important that contact- but I'll also be explaining to you what the quit attempt will involve. you'll still need lots of motivation and lots of support and to see me regularly'				
RC10	Provide information on withdrawal symptoms	Describe to smokers what are and are not nicotine withdrawal symptoms, how common they are, how long they typically last, what causes them and what can be done to alleviate them.	'this leads to the development of withdrawal symptoms and they include a strong urge to smoke and feeling a bit irritable, and of course, if you have a cigarette and those feelings go away and you start to think that smoking actually helps relieve stress but it's really just relieving your withdrawal symptoms'				
Were any new behaviour change techniques identified in the audio-recording or video that are not already included in the taxonomy? If so, please provide the following information: ⁸							
SUMMARY BCT DESCRIPTION						LINE/PAGE NUMBERS	TOTAL No. CITATIONS
<i>Please add additional rows to the table as necessary.</i>							
Total No. of BCTs		212					

Identified ⁹		
<i>Total No. of BCTs identified addressing function BM¹⁰</i>		53
<i>Total No. of BCTs identified addressing function BS</i>		45
<i>Total No. of BCTs identified addressing function A</i>		27
<i>Total No. of BCTs identified addressing function RD</i>		
<i>Total No. of BCTs identified addressing function RI</i>		
<i>Total No. of BCTs identified addressing function RC</i>		87
COMMENTS ¹⁰		<i>Please list any necessary comments or points of clarification</i>

SCORING CRITERIA- CODING TRANSCRIPTS AND PROTOCOLS OF BEHAVIOURAL SUPPORT FOR SMOKING CESSATION

1. BCT CODE AS SPECIFIED IN THE TAXONOMY OF SMOKING CESSATION BEHAVIOUR CHANGE TECHNIQUES
2. BCT LABEL AS SPECIFIED IN THE TAXONOMY OF SMOKING CESSATION BEHAVIOUR CHANGE TECHNIQUES
3. BCT DESCRIPTION AS DEFINED IN THE TAXONOMY OF SMOKING CESSATION BEHAVIOUR CHANGE TECHNIQUES
4. SCORING CRITERIA
 - a. *0 = Not Used*

Record '0' if the BCT was not applied. A BCT is considered not used if:

 - It does not appear at all in the transcript (unless the transcript is incomplete, in which case please write N/A)
 - It appears only partially, for instance, the practitioner says a few words but doesn't finish the sentence.
 - b. *1 = BCT Used*

Record '1' if the BCT was used. A BCT is considered to be used if:

 - It appears in the transcript at least once in a manner congruent with the BCT description provided.
5. LINE / PAGE NUMBERS
 - For transcripts, record the line numbers where the BCT was used to indicate where the practitioner used the technique. Please record all the line numbers corresponding to all the instances where this technique was used, as the analysis focuses on evidence about use of techniques.
 - For protocols, record the page numbers where the BCT was first used to indicate where the practitioner started to use the technique. Please record all the page numbers corresponding to all the instances where this technique was used, as the analysis focuses on evidence about use of techniques.
6. EXAMPLE/QUOTE
 - For protocols and transcripts please extract quotes as examples of the use of a specific BCT by the practitioner. Quotes should correspond to the line/page numbers provided in the adjacent column to the left of the column provided for example quotes. Please provide quotes verbatim, without altering them or omitting any words. Please extract all instances in which a BCT was applied as quotes, as the analysis focuses on evidence about the use of techniques.
7. TOTAL No. CITATIONS
 - Please sum the total number of times each specific BCT featured in the transcript/protocol and record the final frequency figure in the final column of the coding table.
8. IDENTIFICATION OF NEW/ADDITIONAL BCTs
 - Where you may feel that a new BCT has been applied and featured in the transcript/protocol that is not covered by any of the existing BCTs and the corresponding BCT descriptions included in the taxonomy please provide: a summary description of what you feel the new BCT addresses; a line/page number highlighting where the BCT first featured; please extract

a quote as an example of the application of the new BCT identified; and please sum and state the total number of times the BCT was applied and featured in the transcript/protocol. Please state any additional comments or points of clarification as necessary.

9. TOTAL No. OF BCTs IDENTIFIED

- Please sum the total number of BCTs that featured at least once in the transcript or protocol (max. n= 53)

10. TOTAL No. OF BCTs IDENTIFIED ADDRESSING FUNCTION...

- For each behaviour change function [i.e. addressing motivation (BM), maximizing self-regulatory capacity and skills (BS), promoting adjuvant activities (A), general aspects of the interaction focusing on delivery of the intervention (RD), general aspects of the interaction focusing on information gathering (RI), general aspects of the interaction focusing on general communication (RC)] please sum the total number of BCTs corresponding to that function that featured at least once in the transcript/protocol.

11. COMMENTS

- Please list any comments you may have or points of clarification (e.g. highlight instances where you may feel a technique was covered but with slightly different wording or focus from the BCT description provided)

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Appendix 2: BCTs and total number of citations identified in the NCSCT transcripts

BCT Code	BCT label	BCT definition	Total No. Citations
BM1	Provide information on consequences of smoking and smoking cessation	Give, or make more salient, information about the harm caused by smoking and the benefits of stopping or staying quit; distinguish between the harms from smoking and nicotine; debunk myths about low tar and own-roll cigarettes and cutting down	3
BM2	Boost motivation and self efficacy	Give encouragement and bolster confidence in ability to stop	10
BM3	Provide feedback on current behaviour and progress	Give feedback arising from assessment of current self-reported or objectively monitored behaviour (e.g. expired-air CO) and/or progress towards becoming a permanent non-smoker	8
BM4	Provide rewards contingent on successfully stopping smoking	Give praise or other rewards if the person has not smoked	4
BM5	Provide normative information about others' behaviour and experiences	Give information about how the smoker's experience compares with other people's	17
BM6	Prompt commitment from the client there and then	Encourage the smoker to affirm or reaffirm a strong commitment to start, continue or restart the quit attempt	4
BM7	Provide rewards contingent on effort or progress	Give praise or other rewards for the effort the smoker is making and if the smoker has engaged in activities such as correct use of medication that aid cessation	7
BM8	Strengthen ex-smoker identity	Explain the importance of regarding smoking as something that is 'not an option', including the 'not a puff' (NAP) rule, encourage the smoker to re-evaluate the attraction to smoking, and construct a new identity as someone who 'used to smoke'	11
BM9	Conduct motivational interviewing	Adopt a formal motivational interviewing protocol	5
BM10	Identify reasons for wanting and not wanting to stop smoking	Help the smoker to arrive at a clear understanding of his or her feelings about stopping smoking, why it is important to stop and any conflicting motivations	4
BM11	Explain the importance of abrupt cessation	Explain why it is better to stop abruptly rather than cut down gradually if at all possible	1
BM12	Measure carbon monoxide (CO)	Measure expired air CO to assess extent of smoke exposure prior to quitting and to confirm successful abstinence; use the measurement as a motivational tool	0

Specific focus on behavior (B) maximising self-regulatory capacity/skills (S)

BS1	Facilitate barrier identification and problem solving	Help the smoker to identify general barriers (e.g. susceptibility to stress) that might make it harder to stay off cigarettes and develop general ways of addressing these	6
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BS2	Facilitate relapse prevention and coping	Help the smoker understand how lapses occur and how they lead to relapse and to develop specific strategies for preventing lapses or avoiding lapses turning into relapse	3
BS3	Facilitate action planning/develop treatment plan	Work with smoker to generate a clear quit plan including preparations for the quit attempt (e.g. obtaining medication)	2
BS4	Facilitate goal setting	Help the smoker to set a quit date and goals that support the aim of remaining abstinent	8
BS5	Prompt review of goals	Review how far the smoker has achieved the main goal of abstinence and any other goals that are supportive of it (e.g. putting in place plans to avoid triggers)	6
BS6	Prompt self-recording	Help the smoker to establish a routine of recording potentially useful information (e.g. situations or times when urges are strong and less strong)	0
BS7	Advise on changing routine	Advise on ways of changing daily or weekly routines to minimise exposure to smoking cues	0
BS8	Advise on environmental restructuring	Advise on ways of changing the physical environment to minimise exposure to smoking cues (e.g. removing ashtrays from the house) or to provide cues to sustain quitting	3
BS9	Set graded tasks	Set small achievable goals where appropriate (e.g. take one day at a time)	0
BS10	Advise on conserving mental resources	Advise on ways of minimising stress and other demands on mental resources (activities that require mental effort)	3
BS11	Advise on avoidance of cues for smoking	Give specific advice on how to avoid being exposed to social or other cues for smoking (e.g. staying away from places where people smoke)	1
BS12	Facilitate restructuring of social life	Advise on ways of changing social interactions with family, friends and colleagues so that they support, rather than interfere with, the goal of remaining abstinent	2
BS13	Advise on methods of weight control	Advise on ways of minimising weight gain that do not increase motivation to smoke (e.g. take exercise, carry around 'healthy snacks')	0
BS14	Teach relaxation techniques	Teach specific relaxation techniques and how and when to apply them	0

Promote adjuvant activities (A)

A1	Advise on stop-smoking medication	Explain the benefits of medication, safety, potential side effects, contra-indications, how to use them most effectively, and how to get them; advise on the most appropriate medication for the smoker and promote effective use	24
A2	Advise on/facilitate use of social support	Advise on or facilitate development of social support from friends, relatives, colleagues or 'buddies'	7
A3	Adopt appropriate local procedures to enable clients to obtain free medication	Enact the necessary procedures of a Stop Smoking Service to ensure that the smoker gets his/her medication easily and without charge where appropriate	0
A4	Ask about experiences of stop smoking medication that the smoker is using	Assess usage, side effects and benefits experienced of medication(s) that the smoker is currently using	4
A5	Give options for additional and later	Give information about options for additional support outside the programme where these are available (e.g. websites, self-help groups, telephone helpline)	0

support

General aspects of the interaction (R) focusing on delivery of the intervention (D)			
RD1	Tailor interactions appropriately	Use relevant information from the client to tailor the behavioural support provided	1
RD2	Emphasise choice	Emphasise client choice within the bounds of evidence based practice	0
General aspects of the interaction (R) focusing on information gathering (I)			
RI1	Assess current and past smoking behaviour	Assess amount smoked, age when started, pattern of smoking behaviour	6
RI2	Assess current readiness and ability to quit	Assess current level of motivation to stop and confidence in success	1
RI3	Assess past history of quit attempts	Assess number and duration of past quit attempts and experiences related to these, including factors that led back to smoking	2
RI4	Assess withdrawal symptoms	Assess the presence and severity of nicotine withdrawal signs and symptoms	1
RI5	Assess nicotine dependence	Assess the degree of nicotine dependence	2
RI6	Assess number of contacts who smoke	Assess how many friends, relatives and work colleagues smoke	1
RI7	Assess attitudes to smoking	Assess positive and negative beliefs and feelings about smoking	0
RI8	Assess level of social support	Assess the extent to which friends, relatives and work colleagues will be supportive of the quit attempt and more generally	2
RI9	Explain how tobacco dependence develops	Explain the process by which smokers become addicted to cigarettes and the role that nicotine plays in this	4
RI10	Assess physiological and mental functioning	Assess physiological functioning such as lung function and mental states such as anxiety and depression levels	0
General aspects of the interaction (R) focusing on general communication (C)			
RC1	Build general rapport	Establish a positive, friendly and professional relationship with the smoker and foster a sense that the smoker's experiences are understood	4
RC2	Elicit and answer questions	Prompt questions from the smoker and answer clearly and accurately	6
RC3	Explain the purpose of CO monitoring	Explain to the smoker the reasons for measuring CO at different time points, e.g. before and after the quit date	3
RC4	Explain expectations regarding treatment programme	Explain to the smoker the treatment programme, what it involves, the active ingredients and what it requires of the smoker	8
RC5	Offer/direct towards appropriate written materials	Distinguish what are, and are not, appropriate written materials and offer/direct clients to these in ways that promote their effective use	0

RC6	Provide information on withdrawal symptoms	Describe to smokers what are, and are not, nicotine withdrawal symptoms, how common they are, how long they typically last, what causes them and what can be done to alleviate them	9
RC7	Use reflective listening	Adopt a style of interaction that involves listening carefully to the smoker and where appropriate reflecting back to the smoker key elements of what s/he is saying	8
RC8	Elicit client views	Prompt the client to give views on smoking, smoking cessation and any aspects of the behavioural support programme	3
RC9	Summarise information / confirm client decisions	Provide a summary of information exchanged and establish a clear confirmation of decisions made and commitments entered into	3
RC10	Provide reassurance	Give general reassurance to the smoker that his/her experiences are normal and time limited, and provide positive expectations of success based on experience with other smokers in the same situation	7

Appendix 3: Full list of adaptations to the original published taxonomy of smoking cessation

BCTs

BCT Code	BCT Label	Original BCT description	Adaptation
BM1	Provide information on the consequences of smoking and smoking cessation	Give, or make more salient, information about the harm caused by smoking and the benefits of stopping; distinguish between the harms from smoking and nicotine; debunk myths about low tar and own-roll cigarettes and <u>cutting down</u>	<i>Existing BCT description refined for clarification purposes; ‘cutting down’ removed as conflicted with BM10- explain importance of abrupt cessation.</i>
BM2	Boost motivation and self-efficacy	Give encouragement and bolster confidence in ability to stop. <u>Can include</u> telling the person that they can successfully stop smoking, arguing against self-doubts and asserting that they can and will succeed.	<i>Existing BCT description refined for clarification purposes.</i>
BM4	Provide rewards contingent on <u>successfully stopping smoking not smoking</u>	Give praise or rewards if the person has not smoked.	<i>Existing BCT label was refined to greater reflect the corresponding BCT description. The BCT description implies that this BCT is not necessarily about a successful quit attempt but rather about ‘not smoking.’ ‘Successfully stopping smoking’ was omitted to clarify.</i>
BM5	Provide normative information about others’ behaviour and experiences	Give information about how the smoker’s experience compares with other people’s. <u>Involves providing information about how the smoker’s experience compares with that of other smokers who are trying to quit, as to indicate that a particular behaviour or sequence of behaviours are common, or uncommon, amongst other smokers trying to quit.</u>	<i>Existing BCT description expanded to include a clearer, more detailed definition adopted from other existing taxonomies of BCTs (Michie and Abraham, 2008) for clarification and understanding purposes.</i>
BM8	Strengthen ex-smoker identity	Explain the importance of regarding smoking that is ‘not an option,’ including the ‘not a puff’ rule, encourage the smoker to re-evaluate the attraction to smoking, and construct a new identity as someone who ‘used to smoke.’	<i>Existing BCT description refined. Text was removed to minimize confusion with BCT BM9- help identify reasons for wanting and not wanting to stop smoking.</i>
BM9	Help Facilitate identification of reasons for wanting and not wanting to stop smoking	Help the smoker to arrive at a clear understanding of his or her feelings about stopping smoking, why it is important to stop and any conflicting motivations.	<i>BCT label refined.</i>

BM11	Measure CO <u>and explain the purposes of CO monitoring</u>	Measure expired- air carbon monoxide concentration <u>and explain to the smoker the reasons for measuring CO at different time points (e.g. before and after the quit date)</u>	<i>Originally separate BCTs BM11 (measure CO) and RC3 (explain purpose of CO monitoring) were merged together as they typically co-occur together in practice.</i>
RC3			
[previously]			
BM12	Conduct motivational interviewing	<u>Adopt a formal motivational interviewing protocol</u>	<i>Description created.</i>
BS1	Facilitate barrier identification and problem solving	Help the smoker identify general barriers that might make it harder to stay off cigarettes (e.g. susceptibility to cigarettes). Help the smoker develop general ways of addressing and overcoming these, and increasing facilitators (e.g. by generating alternative courses of action and pros and cons of each and weighing them up)	<i>Existing BCT description expanded to better differentiate between BCTs BS1, BS2 and BS3. Definitions expanded using BCT descriptions from other taxonomies of BCTs.</i>
BS2	Facilitate relapse prevention and coping	Help the smoker understand how lapses occur and how they lead to relapse. <u>Plan how to maintain behaviour that has changed, by helping identify in advance situations in which the changed behaviour may not be maintained,</u> and develop specific strategies for preventing lapses or avoiding lapses turning into relapse.	<i>Existing BCT description expanded to better differentiate between BCTs BS1, BS2 and BS3. Definitions expanded using BCT descriptions from other taxonomies of BCTs.</i>
BS5	Prompt review of set goals	Review how far the smoker has achieved the main goal of abstinence and any other goals that are supportive of it (e.g. putting in place plans to avoid triggers). <u>In most cases this will follow previous goal setting and an attempt to act on those goals, followed by a version of revision or readjustment of goals and/or means to attain them.</u>	<i>Existing BCT description expanded using BCT descriptions from other taxonomies for clarification and understanding purposes.</i>
BS8	Advise on environmental restructuring	Advise on ways of changing the <u>physical</u> environment to minimize exposure to physical smoking cues (e.g. removing ashtrays from the house)	<i>Existing BCT description refined. 'Physical' added to the description to help further differentiate this BCT from BS11- advise on avoidance of social cues for smoking</i>
BS12	Facilitate restructuring of social life	Advise on ways of changing social interactions so that they support rather than interfere with smoking cessation	<i>Description created.</i>
BS13	Advise on methods of weight control	Advise on methods of weight control, including diet and/or exercise	<i>Description created.</i>

BS14	Teach relaxation techniques	Teach specific relaxation techniques and how and when to apply them	<i>Description created.</i>
A1 A3 [previously]	Advise on stop smoking medication	<p><u>Includes one or more of the following:</u></p> <ul style="list-style-type: none"> - <u>explaining the benefits of medication, safety, potential side-effects, contra-indications, how to use them most effectively.</u> - <u>advising on the most appropriate medication for the smoker</u> - <u>promoting effective use</u> - <u>explaining how to obtain medications, enacting the necessary procedures to ensure the smoker gets their medication easily and without charge where appropriate</u> 	<i>Originally separate BCTs A1 (advising on stop smoking medication) and A3 (adopt appropriate local procedures to enable clients to obtain free medication) were merged, as they typically co-occur.</i>
RC2 Merge of previous BCTs: RC2, RC7, RC9, RC8	<u>General practitioner communication approaches</u>	<u>Communication that Includes one or more of the following: eliciting and answering questions, using reflective listening, summarizing information, and confirming client decisions</u>	<i>New BCT label was created by merging several BCTs such as eliciting and answering questions, using reflective listening, summarizing information, and elicit client views which are just general communication techniques. These occurred throughout the entire NCSCCT scripts as part of normal conversation and interaction, and coding each instance of each communication technique would be repetitive and not very informative.</i>
RC3	Emphasise choice	Emphasise client choice within bounds of evidence based practice	<i><u>BCT moved from sub-function RD to function RC.</u></i>
RC5	Tailor interactions appropriately	Use relevant information from the client to tailor the behavioural support provided	<i><u>BCT moved from sub-function RD to function RC.</u></i>
RC7 Merge of previous	Information gathering and assessment	<p>Any information gathering that provides the practitioner with the knowledge needed from the client for appropriate behaviour change techniques to be delivered.</p> <p>Includes one or more of the following:</p> <ul style="list-style-type: none"> - Assessing current and past smoking behaviour - Assessing current readiness and 	<i>BCTs merged/ New BCT label created. All previous assessment related BCTs originally under the information gathering behaviour change sub-function (RI) were merged to form one large information gathering for</i>

BCTs:		ability to quit	<i>simplification purposes.</i>
		- Assessing past history of quit attempts	
		- Assessing withdrawal symptoms	
RI1, RI1,		- Assessing nicotine dependence	
RI3, RI4,		- Assessing number of contacts who smoke	
RI5, RI6,		- Assessing attitudes to smoking	
RI7, RI8,		- Assessing level of social support	
RI10		- Assessing physiological and mental functioning	
RC8	Explain how tobacco dependence develops	<u>Give an explanation of the development of tobacco dependence and the effect of nicotine</u>	<i>Description created. Moved from BCT sub-function RI to function RC.</i>

Appendix 4: Types of adaptations to the original taxonomy of smoking cessation BCTs

Type of Adaptation	No. of BCTs applied to	Example
Merging theoretically similar and/or co-occurring BCTs	17	Merged BM11 (Measure CO) and RC3 (Explain purposes of CO monitoring)
Expand/refine existing BCT definitions	11	BS5 Prompt review of set goals: ‘Review how far the smoker has achieved the main goal of abstinence and any other goals supportive of it. [Expanded to include] <i>In most cases this will follow previous goal setting and an attempt to act on those goals, followed by a version of revision or readjustment of goals and/or means to attain them.</i>
Create new BCT definitions where previously unavailable	8	BS12 Facilitate restructuring social life: ‘advise on ways of changing social interactions so they support rather than interfere with smoking cessation.

Appendix 5. Session characteristics and the proportion of BCTs specified in the treatment manuals delivered individual behavioural support sessions; presented by Stop Smoking Service and according to session type.

Service ID	Session ID (Service No./ Transcript No.)	Practitioner ID (Service No./ Transcript No.)	Session type (1=pre-quit; 2=quit-day; 3=post-quit)	Duration (Min.Sec)	Number of BCTs in Manual (according to session type)	Number of manual specified BCTs in Session (%)	Total Number of BCTs in session	Number non-manual specified BCTs in session (% total BCTs)
<i>Service 1 (n=21 transcripts)</i>								
S01	S01T01	S01P01	3	10.59	10	8 (80%)	14	6 (43%)
S01	S01T02	S01P01	3	9.36	10	6 (60%)	17	11 (65%)
S01	S01T03	S01P01	3	8.09	10	8 (80%)	21	13 (61%)
S01	S01T04	S01P01	3	12.27	10	9 (90%)	22	13 (59%)
S01	S01T08	S01P02	3	5.01	10	5 (50%)	8	3 (34%)
S01	S01T10	S01P02	3	5.15	10	6 (60%)	11	5 (45%)
S01	S01T11	S01P02	3	7.19	10	7 (70%)	21	14 (66%)
S01	S01T07	S01P03	2	16.46	8	6(75%)	27	21 (78%)
S01	S01T09	S01P03	1	36.36	13	9 (69%)	25	16 (64%)
S01	S01T14	S01P03	3	17.00	10	5(50%)	22	17 (77%)
S01	S01T15	S01P03	3	11.01	10	8 (80%)	22	14 (64%)
S01	S01T16	S01P03	3	18.21	10	8 (80%)	23	15 (65%)
S01	S01T06	S01P04	3	16.57	10	4 (40%)	23	19 (82%)
S01	S01T12	S01P04	2	20.32	8	4 (50%)	19	15 (79%)
S01	S01T13	S01P04	1	22.19	13	9(69%)	17	8 (47%)
S01	S01T14	S01P04	1	29.35	13	5 (38%)	20	15 (75%)
S01	S01T18	S01P04	3	13.51	10	8 (80%)	26	18 (69%)
S01	S01T21	S01P04	1	26.45	13	7 (54%)	25	18(72%)
S01	S01T05	S01P05	3	5.45	10	5 (50%)	14	9 (64%)
S01	S01T19	S01P05	3	21.50	10	9(90%)	22	13(59%)

S01	S01T20	S01P05	3	15.14	10	8(80%)	24	16 (67%)
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Service 2(n=13 transcripts)

S02	S02T08	S02P01	3	5.17	17	6 (35%)	12	6 (50%)
S02	S02T10	S02P01	3	14.22	17	11(64%)	20	9 (45%)
S02	S02T11	S02P01	3	8.01	17	8 (47%)	20	12 (60%)
S02	S02T06	S02P02	2	20.17	21	16(76%)	27	11 (41%)
S02	S02T13	S02P02	3	11.45	17	11(64%)	23	12 (52%)
S02	S02T01	S02P03	1	12.10	12	8 (67%)	23	15 (65%)
S02	S02T02	S02P03	1	5.47	12	10 (83%)	18	8 (44%)
S02	S02T03	S02P03	1	17.48	12	10 (83%)	25	15 60%
S02	S02T09	S02P03	3	8.09	17	11 (64%)	22	11 (50%)
S02	S02T04	S02P04	1	15.46	12	8 (67%)	26	18 (69%)
S02	S02T05	S02P04	2	13.15	21	18(85%)	31	13(42%)
S02	S02T07	S02P04	3	12.31	17	9 (53%)	23	12 (52%)
S02	S02T12	S02P04	3	18.02	17	11 (64%)	21	10 (48%)

Appendix 6: BCTs included in the treatment manual from each Stop Smoking Service.

Note: BCTs presented in bold are present in both manuals in the relevant sub-section

Session Type	BCTs in manual from Service 1	BCTs in manual from Service 2
Pre-quit	<ul style="list-style-type: none"> - Measure and explain purpose of CO monitoring - Action planning - Advise on stop smoking medications - Information gathering and assessment - Explain expectations regarding the treatment programme - Offer/direct towards appropriate written materials - Build rapport - Advise on use of social support - Prompt commitment from the client there and then - Advise on environmental restructuring - General practitioner communication approaches - Provide reassurance - Goal setting 	<ul style="list-style-type: none"> - Measure and explain purpose of CO monitoring - Action planning - Advise on stop smoking medications - Information gathering and assessment - Explain expectations regarding the t - Offer/direct towards appropriate written materials - Identify reasons for wanting/not wanting to stop smoking - Facilitate relapse prevention and coping - Prompt review of set goals - Prompt self-recording - Advise on changing routines - Set graded tasks
Quit-day	<ul style="list-style-type: none"> - Measure and explain purpose of CO monitoring - Facilitate relapse prevention and coping - Ask about experiences of stop-smoking medications the client is currently using - Build rapport - Information gathering and assessment - Goal setting - Prompt review of set goals - Provide options for additional/later support 	<ul style="list-style-type: none"> - Measure and explain purpose of CO monitoring - Facilitate relapse prevention and coping - Ask about experiences of stop-smoking medications the client is currently using - Build rapport - Information gathering and assessment - Boost motivation and self-efficacy - Prompt commitment from the client there and then - Strengthen ex-smoker identity - Identify reasons for wanting/not wanting to stop smoking - Distract from motivation to engage in behaviour - Barrier identification and problem solving - Action planning - Prompt self-recording - Advise on environmental-restructuring - Advise on avoidance of cues for smoking - Advise on stop smoking medications - Advise on use of social support - Explain expectations regarding the treatment programme - Offer/direct towards appropriate written materials

Post-quit

- Provide rewards contingent on successfully stopping smoking
 - Provide rewards contingent on effort or progress
 - Measure and explain purpose of CO monitoring
 - Facilitate relapse prevention and coping
 - Advise on stop smoking medications
 - Ask about experiences of stop smoking medications that the client is currently using
 - Prompt review of set goals
 - Information gathering and assessment
 - Build rapport
 - Offer/direct towards appropriate written materials
- General practitioner communication approaches
 - Provide reassurance
- Provide rewards contingent on successfully stopping smoking
 - Provide rewards contingent on effort or progress
 - Measure and explain purpose of CO monitoring
 - Facilitate relapse prevention and coping
 - Advise on stop smoking medications
 - Ask about experiences of stop smoking medications that the client is currently using
 - Prompt review of set goals
 - Provide information on the consequences of smoking and smoking cessation
 - Prompt commitment from the client there and then
 - Strengthen ex-smoker identity
 - Barrier identification and problem solving
 - Goal setting
 - Advise on use of social support
 - Provide options for additional/later support
 - Emphasise choice
 - General practitioner communication approaches
 - Provide reassurance
-

Appendix 7: Proportion of behavioural support sessions each manual-specified BCT was delivered in according to session type (pre-quit, quit-day, post-quit), presented combined for both services.

BCT Label	No. pre-quit sessions delivered in according to pre-quit manual specification	No. quit-day sessions delivered in according to quit-day manual specification	No. post-quit sessions delivered in according to post-quit manual specification	Total No. sessions BCT delivered in according to manual specification (max n=34)
Provide rewards contingent on successfully stopping smoking	-*	-	13/22	13/22 (59%)
Provide rewards contingent on effort or progress	-	-	18/22	18/22 (82%)
Identify reasons for wanting/not wanting to stop smoking	4/4 (100%)	1/2 (50%)	4/7	9/13 (69%)
Measure CO and explain purpose of CO monitoring	8/8 (100%)	4/4 (100%)	18/22 (82%)	30/34 (88%)
Facilitate relapse prevention and coping	0/4 (0%)	1/4 (25%)	9/22 (41%)	10/30 (33%)
Facilitate action planning/ develop treatment plan	6/8 (75%)	2/2 (100%)	-	8/10 (80%)
Facilitate goal setting	-	2/2 (100%)	1/7 (14%)	3/9 (33%)
Prompt review of set goals	0/4 (0%)	0/2 (0%)	15/22 (68%)	15/28 (53%)
Prompt self-recording	3/4 (75%)	1/2 (50%)	-	4/6 (67%)
Advise on changing routine	2/4 (50%)	-	-	2/4 (50%)
Advise on environmental restructuring	2/4 (50%)	2/2 (100%)	-	4/6 (67%)
Set graded tasks	0/4 (0%)	-	-	0/4 (0%)
Advise on stop smoking medication	8/8 (100%)	4/4 (100%)	20/22 (91%)	32/34 (94%)

Ask about experience of stop smoking medications the smoker is using	0/4 (0%)	4/4 (100%)	18/22 (82%)	22/30 (73%)
Build rapport	4/4 (100%)	2/2 (100%)	14/15 (93%)	20/21 (95%)
Explain expectations regarding the treatment programme	8/8 (100%)	1/2 (50%)	-	9/10 (90%)
Offer/direct towards appropriate written materials	5/8 (63%)	2/2 (100%)	0/15 (0%)	7/25 (28%)
Information gathering and assessment	8/8 (100%)	4/4 (100%)	-	12/12 (100%)
Provide reassurance	2/4 (50%)	2/2 (100%)	4/7 (57%)	8/13 (62%)
General practitioner communication approaches	4/4 (100%)	2/2 (100%)	7/7 (100%)	13/13 (100%)
Emphasise choice	-	-	2/7 (29%)	2/7 (29%)
Give options for additional/later support	-	-	3/7 (43%)	3/7 (43%)
Advise on/facilitate use of social support	1/4 (25%)	1/2 (50%)	0/7 (0%)	2/13 (15%)
Advise on avoidance of cues for smoking	-	2/2 (100%)	-	2/2 (100%)
Facilitate barrier identification and problem solving	-	1/2 (50%)	5/7 (71%)	6/9 (67%)
Distract from motivation to engage in behaviour	-	1/2 (50%)	-	1/2 (50%)
Strengthen ex-smoker identity	-	2/2 (100%)	-	2/2 (100%)
Prompt commitment from the client there and then	2/4 (50%)	0/2 (0%)	0/7 (0%)	2/13 (15%)
Boost motivation and self-efficacy	-	2/2 (100%)	-	2/2 (100%)
Provide information on the consequences of smoking and	-	-	4/7 (57%)	4/7 (57%)

* ‘-‘ indicates BCT not present in manual in pre-quit, quit-day or post-quit section

Appendix 8: BCTs identified in each section of the service treatment manual.

<p>PRE-QUIT SESSIONS (n=22 BCTs)</p>	<ul style="list-style-type: none"> -Provide information on consequences of smoking and smoking cessation -Boost motivation and self-efficacy -Prompt commitment from the client -Strengthen ex-smoker identity -Explain the importance of abrupt cessation -Measure and explain the purpose of CO monitoring -Facilitate barrier identification and problem solving -Facilitate action planning/develop treatment plan -Facilitate goal-setting -Environmental restructuring -Advise on avoidance of cues for smoking -Advise on stop smoking medications -Facilitate use of social support -Give options for additional and/or later support -Build rapport -general practitioner communication approaches - Emphasise choice -Provide reassurance -Information gathering and assessment -Explain how tobacco dependence develops -Explain expectations regarding the treatment programme -Provide information on withdrawal symptoms
<p>QUIT-DAY SESSIONS (n=25 BCTs)</p>	<ul style="list-style-type: none"> -Boost motivation and self-efficacy -Provide normative information on other smokers' experiences -Prompt commitment from the client -Strengthen ex-smoker identity -Explain the importance of abrupt cessation - Measure and explain the purpose of CO monitoring - Facilitate distraction from motivation to engage in behaviour -Facilitate barrier identification and problem solving -Relapse prevention and coping -Advise on changing routines - Environmental restructuring - Set graded tasks - Advise on avoidance of cues for smoking -Prompt self-reward -Advise on stop smoking medications -Facilitate use of social support -Ask about experiences of stop smoking medications the smoker is currently using -Give options for additional and/or later support -Build rapport -general practitioner communication approaches -Provide reassurance -Information gathering and assessment -Explain how tobacco dependence develops -Explain expectations regarding the treatment programme -Provide information on withdrawal symptoms
<p>POST-QUIT SESSIONS (n=28 BCTs)</p>	<ul style="list-style-type: none"> -Provide information on consequences of smoking and smoking cessation -Boost motivation and self-efficacy -provide feedback on performance -provide rewards contingent on not smoking

	<ul style="list-style-type: none">-provide normative information on other smokers' experiences-Prompt commitment from the client-provide rewards contingent on effort or progress-Strengthen ex-smoker identity-facilitate identification of reasons for wanting and not wanting to stop smoking-Explain the importance of abrupt cessation-Measure and explain the purpose of CO monitoring-Facilitate barrier identification and problem solving-Facilitate action planning/develop treatment plan-Review set goals-Prompt self-recording-Advise on conserving mental resources-Advise on avoidance of cues for smoking- Advise on stop smoking medications-Facilitate use of social support-Ask about experiences of stop smoking medications the smoker is currently using-Give options for additional and/or later support-Build rapport-general practitioner communication approaches-Provide reassurance-Information gathering and assessment-Provide information on withdrawal symptoms-reflective listening
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Appendix 9: Proportion of behavioural support sessions each manual-specified BCT was delivered

in according to session type (pre-quit, quit-day, post-quit).

	No. pre-quit sessions delivered in according to pre-quit manual specification	No. quit-day sessions delivered in according to quit-day manual specification	No. post-quit sessions delivered in according to quit-day manual specification	Total No. sessions BCT delivered in according to manual specification (max=64)
Provide information on the health consequences of smoking and smoking cessation	5/27	-	12/21	17/48 (35%)
Boost motivation and self-efficacy	20/27	8/16	14/21	42/64 (66%)
Provide feedback on current behaviour and progress	-	-	18/21	18/21 (86%)
Provide rewards contingent on not smoking	-	-	9/21	9/21 (43%)
Provide normative information about others' behaviour and experiences	19/27	9/16	13/21	41/64 (64%)
Prompt commitment from the client there and then	2/27	0/16	0/21	2/64 (3%)
Provide rewards contingent on effort or progress	-	-	14/21	14/21 (67%)
Strengthen ex-smoker identity	2/27	6/16	9/21	17/64 (27%)
Facilitate identification of reasons for wanting and not wanting to stop smoking	-	-	9/21	9/21 (43%)
Explain the importance of abrupt cessation	2/27	0/16	2/21	4/64 (6%)
Measure CO and explain the purposes of CO monitoring	1/27	0/16	0/21	1/64 (2%)
Distract from motivation to engage in behaviour	-	4/16	-	4/16 (25%)
Facilitate barrier identification and problem solving	10/27	10/16	7/21	27/64 (42%)
Facilitate relapse prevention and coping	-	3/16	5/21	8/37 (22%)
Facilitate action planning/develop a treatment plan	6/27	-	1/21	7/48 (15%)
Facilitate goal setting	22/27	-	-	22/27 (81%)
Prompt review of set goals	-	-	9/21	9/21 (43%)
Prompt self-recording	-	-	2/21	2/21 (10%)
Advise on changing routine	-	3/16	-	3/16 (19%)
Advise on environmental restructuring	4/27	1/16	-	5/43 (12%)
Set graded tasks	-	0/16	-	0/16 (0%)
Advise on conserving mental resources	-	-	3/21	3/21 (14%)
Advise on avoiding social	5/27	0/16	0/21	5/64 (8%)

cues for smoking				
Promote self-reward	-	2/16	-	2/16 (13%)
Advise on stop smoking medication	24/27	13/16	12/21	49/64 (75%)
Advise on/facilitate use of social support	3/27	3/16	2/21	8/64 (13%)
Ask about experiences of stop smoking medication that the smoker is currently using	-	5/16	12/21	17/37 (46%)
Give options for additional and later support	25/27	15/16	21/2	61/64 (95%)
Build general rapport	18/27	8/16	13/21	39/64 (61%)
General communication approaches	17/27	15/16	20/21	52/64 (81%)
Emphasise choice	9/27	-	-	9/27 (33%)
Provide reassurance	17/27	12/16	12/21	41/64 (6%)
Information gathering and assessment	26/27	14/16	16/21	57/64 (88%)
Explain how tobacco dependence develops	7/27	0/16	-	7/43 (16%)
Explain expectations regarding the treatment programme	22/27	6/16	-	28/43 (65%)
Provide information on withdrawal symptoms	7/27	2/16	2/21	11/64 (17%)
reflective listening	-	-	13/21	13/21 (62%)

Appendix 10: Non-manual specified BCTs delivered in behavioural support sessions, presented according to session type and ranked according to frequency of transcripts featured in.

BCT label	Number of transcripts featured in (% of total)
<i>Pre-quit transcripts (max 27)</i>	
‘reflective listening’	22 (81%)
‘Provide rewards contingent on effort or progress’	9 (33%)
‘Promote behavioural substitution’	8 (30%)
‘Facilitate identification of reasons for wanting and not wanting to stop smoking’	7 (26%)
‘Advise on changing routine’	6 (22%)
‘Provide feedback on current behaviour and progress’	4 (15%)
‘Advise on conserving mental resources’	4 (15%)
‘Prompt self-recording’	3 (11%)
‘Facilitate relapse prevention and coping’	2 (7%)
‘Set graded tasks’	2 (7%)
‘Advise on methods of weight control’	2 (7%)
‘Promote self-reward’	2 (7%)
‘Provide rewards contingent on not smoking’	1 (4%)
‘Distract from motivation to engage in behaviour’	1 (4%)
‘Ask about experiences of stop smoking medication that the smoker is currently using’	1 (4%)
<i>Quit-day transcripts (max 16)</i>	
‘Provide feedback on current behaviour and progress’	12 (75%)
‘Facilitate identification of reasons for wanting and not wanting to stop smoking’	12 (75%)
‘Reflective listening’	12 (75%)
‘Provide rewards contingent on effort or progress’	11 (69%)
‘Prompt review of set goals’	11 (69%)
‘Provide information on the health consequences of smoking and smoking cessation’	7 (44%)
‘Emphasise choice’	5 (31%)
‘Facilitate action planning/ develop a treatment plan’	4 (25%)
‘Promote behavioural substitution’	4 (25%)
‘Advise on conserving mental resources’	3 (19%)
‘Facilitate goal setting’	2 (13%)
‘Prompt self-recording’	2 (13%)
‘Advise on methods of weight control’	2 (13%)
<i>Post-quit transcripts (max 21)</i>	
‘Distract from motivation to engage in behaviour’	6 (29%)
‘Promote self-reward’	4 (19%)
‘Facilitate goal setting’	4 (19%)

‘Advise on changing routine’	4 (19%)
‘Emphasise choice’	3 (14%)
‘Advise on environmental restructuring’	2 (10%)
‘Advise on methods of weight control’	2 (10%)
‘Promote behavioural substitution’	2 (10%)
‘Explain expectations regarding the treatment programme’	2 (10%)
‘Teach relaxation techniques’	1 (5%)
‘Offer/direct towards appropriate written materials’	1 (5%)
‘Explain how tobacco dependence develops’	1 (5%)



RESEARCH

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Assessing fidelity of delivery of smoking cessation behavioural support in practice

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Abstract

Background: Effectiveness of evidence-based behaviour change interventions is likely to be undermined by failure to deliver interventions as planned. Behavioural support for smoking cessation can be a highly cost-effective, life-saving intervention. However, in practice, outcomes are highly variable. Part of this may be due to variability in fidelity of intervention implementation. To date, there have been no published studies on this. The present study aimed to: evaluate a method for assessing fidelity of behavioural support; assess fidelity of delivery in two English Stop-Smoking Services; and compare the extent of fidelity according to session types, duration, individual practitioners, and component behaviour change techniques (BCTs).

Methods: Treatment manuals and transcripts of 34 audio-recorded behavioural support sessions were obtained from two Stop-Smoking Services and coded into component BCTs using a taxonomy of 43 BCTs. Inter-rater reliability was assessed using percentage agreement. Fidelity was assessed by examining the proportion of BCTs specified in the manuals that were delivered in individual sessions. This was assessed by session type (i.e., pre-quit, quit, post-quit), duration, individual practitioner, and BCT.

Results: Inter-coder reliability was high (87.1%). On average, 66% of manual-specified BCTs were delivered per session (SD 15.3, range: 35% to 90%). In Service 1, average fidelity was highest for post-quit sessions (69%) and lowest for pre-quit (58%). In Service 2, fidelity was highest for quit-day (81%) and lowest for post-quit sessions (56%). Session duration was not significantly correlated with fidelity. Individual practitioner fidelity ranged from 55% to 78%. Individual manual-specified BCTs were delivered on average 63% of the time (SD 28.5, range: 0 to 100%).

Conclusions: The extent to which smoking cessation behavioural support is delivered as specified in treatment manuals can be reliably assessed using transcripts of audiotaped sessions. This allows the investigation of the implementation of evidence-based practice in relation to smoking cessation, a first step in designing interventions to improve it. There are grounds for believing that fidelity in the English Stop-Smoking Services may be low and that routine monitoring is warranted.

Keywords: Behaviour change interventions, Smoking cessation, Delivery, Fidelity, Implementation

Introduction

Behavioural support for smoking cessation can be a highly cost-effective, life-preserving intervention [1-3]. It consists of advice, discussion, and targeted activities designed to minimize smokers' motivation to smoke, maximize resolve not to smoke, help with strategies to minimize exposure to smoking cues, cope with urges when they occur, and

make best use of adjunctive activities, such as smoking cessation medications [4-6]. With the growing emphasis on promoting evidence-based practice, behavioural support interventions shown to be effective in research trials have been increasingly implemented as part of routine healthcare practice in numerous high and middle income countries [7]. For instance, in the UK, implementation is via a network of locally organized Stop-Smoking Services, which offer smokers who are trying to quit medication and, typically, four free, weekly behavioural support sessions. Smokers engaging with these services are on average four times more likely to quit [8].

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The translation of clinical research findings into practice is not straightforward, and is often slow and unpredictable [9]. Methods are needed to promote the consistent, systematic uptake of research findings concerning the evidence-base of behaviour change interventions into routine practice [9]. Treatment manuals represent one potential vehicle by which the content of interventions with demonstrated effectiveness may be translated into the content of clinical practice. The term 'treatment manual' typically refers to structured, procedural books outlining the rationale and goals of an intervention, as well as the recommended content (i.e., behaviour change techniques) to be delivered when administering an intervention [10]. Use of manuals offer numerous advantages for clinical practice; they aid the dissemination and replication of interventions, make the content of time-limited interventions more structured and focused than they might be otherwise, and facilitate training and supervision of intervention providers [10,11]. The recent increase in the pressure to employ treatment manuals has extended beyond controlled research trials into practice, and evidence is emerging, supporting the use of manuals in clinical practice [11,12].

Treatment manuals are widely used in the delivery of smoking cessation behavioural support interventions. In the UK, national guidelines outlining the recommended content and format of smoking cessation behavioural support sessions have been published [13]. These recommend that evidence-based guidelines [14] should inform how behavioural support is delivered by the English Stop-Smoking Services. Most of these services have a treatment manual providing standardized guidance for practitioners regarding the specific content to be delivered in different types of behavioural support sessions (i.e., pre-quit, quit-day and post-quit). However, there is evidence that different stop-smoking practitioners providing support in English Stop-Smoking Services and operating to the same treatment manual can have widely differing success rates [15]. This raises an important question as to how far behavioural support is delivered according to specification in treatment manuals, and whether practitioners are adhering to, or deviating from, manual-based treatment specifications. This paper reports an evaluation of a method for assessing this and preliminary results of its application in routine clinical practice.

Fidelity of intervention delivery refers to the extent to which interventions are delivered as intended, with adherence to specifications in intervention manuals [16,17]. It specifically concerns whether core, prescribed intervention components are delivered, rather than the separate but associated question of how components are delivered, for example, in terms of quality or tailoring of delivery. Assessing fidelity of delivery is part of the continuous assessment, monitoring and improvement of the reliability

and internal validity of an intervention [16]. Verifying the extent to which intervention content is delivered according to manual specification is critical for the accurate interpretation of intervention outcomes [16,18]. Assessing fidelity can also highlight both provider training needs and aspects of intervention delivery that require improvement. The need to examine fidelity has been underlined in the CONSORT statement for reporting complex, non-pharmacological interventions [19].

Although the importance of examining fidelity of delivery is widely recognised, reviews to date suggest that it is not frequently assessed, reported, or accounted for in analyses [16,18,20,21]. To date, research efforts have primarily focused on the development and evaluation of new interventions rather than monitoring and improving the fidelity with which interventions are delivered when subsequently implemented in practice [9]. Recommendations of methods for assessing fidelity are widely available [16-18], but these are rarely applied. Recently developed methods for assessing the fidelity of delivery of behaviour change interventions for physical activity [22] and excessive alcohol use [23] use the recommended 'gold standard' strategy of objectively verifying delivery by comparing the content of recorded intervention sessions to pre-specified criteria, such as an intervention manual [16]. Where fidelity of delivery has been assessed, it is often found to be poor (<55%) and rarely uniform [18,20-23]. There is currently no standard method for assessing fidelity of delivery of smoking cessation behaviour change interventions.

The recent development of a theory-linked taxonomy of 43 smoking cessation BCTs has provided a reliable method for specifying the content of behavioural support interventions in terms of their component BCTs [24]. Each BCT has specified criteria for its operationalization, is defined using consistent terminology, and has a clear label that can be used to categorize and consistently report intervention components. A total of 14 BCTs from the taxonomy have been supported by RCT evidence, and 16 have been shown to be significantly associated with improved four-week CO-validated quit outcomes [25,26]. This taxonomy has been reliably applied in a previous study as a coding framework for identifying and categorizing component BCTs present in English Stop-Smoking Service treatment manuals [4,6,25] and transcripts of audio-recorded behavioural support sessions delivered by these services [27]. However, the taxonomy has not yet been used to compare the content of treatment manuals with the transcripts of corresponding behavioural support sessions to assess fidelity.

This study aimed to evaluate the taxonomy as a method for investigating variations in the fidelity of delivery of smoking cessation behavioural support delivered in two English Stop-Smoking Services. In addition to examining

the extent to which manual-specified content is delivered, this study was designed to investigate delivery of BCTs not specified in manuals. Examining additional content is important, as such content introduces further variability in practice and outcomes. Additional content may augment or detract from manual-specified content.

The specific objectives of this study were:

1. To evaluate a method of assessing fidelity of behavioural support for smoking cessation using a taxonomy of behaviour change techniques;
2. To assess using this method the fidelity of delivery of behavioural support in two English Stop-Smoking Services;
3. To examine variation in fidelity according to: session type (i.e., pre-quit, quit-day, post-quit); session duration; stop smoking practitioner; and the specific BCT;
4. To assess the extent of use of BCTs not included in the particular treatment manual in operation.

Methods

Ethical approval

This study received ethical approval by the Clinical, Educational, and Health Psychology Research Department Ethics Committee (UCL) [Reference: CEHP/2011/038].

Design

This observational study assessed fidelity of delivery by comparing the content, in terms of component BCTs, of treatment manuals with the corresponding transcripts of audio-recorded behavioural support sessions.

Study sample and materials

Data were obtained from two English Stop-Smoking services, which typically offer medication and four weekly behavioural support sessions. Behavioural support is typically provided by trained, specialist advisors, often of multidisciplinary backgrounds (i.e., nurses, midwives, GPs, pharmacists). The first session is typically a 'pre-quit session,' which aims to enhance a smoker's motivation and self-confidence to quit, set clear goals, discuss medication options, and address general preparations for quitting. The second session is the 'quit-day' session, which focuses on general strategies for avoiding smoking cues and overcoming barriers to cessation, as well as maintaining motivation and self-efficacy. The final two sessions are post-quit sessions, which concentrate on equipping the client with strategies for avoiding smoking in the long term by facilitating relapse prevention and coping, alongside promoting an ex-smoker identity. Service 1 is based in the north of England and has the highest CO-validated four-week quit rate of 59% (April to December 2011). Service 2 is based in North East London, UK, and has an average CO-validated four-week quit rate

of 38% (April to December 2011). The average CO-validated quit rate in the Stop-Smoking Services in April to December 2011 was 35%, range 5% to 59% [28].

The treatment manual was obtained from each service. A treatment manual was defined as any guidance document providing a 'formal, written plan specifying procedures to be followed in providing a specific treatment or support for smoking cessation to smokers' [6]. Manuals are usually written in-house by each service and typically outline the specific content to be delivered by practitioners in either a pre-quit, quit-day or post-quit behavioural support session. Manuals therefore represent 'recommended' practice, and in theory incorporate national guidance and training standards [13,29].

Audio recordings of consecutive behavioural support sessions delivered to consenting clients as part of routine clinical practice were obtained during a two-month data collection period. This minimized the opportunity for practitioners to select which clients to record. The resulting sample comprised 30 recordings from Service 1, and 13 recordings from Service 2. Nine audio recordings from Service 1 were excluded from analysis as they were incomplete. A mixture of session types (pre-quit, quit day, and post-quit) were audio recorded by the practitioner using a discrete recording device. Of the 21 usable recordings from Service 1, 4 were of pre-quit sessions, 2 quit-day, and 15 post-quit. For Service 2, 4 recordings were of pre-quit sessions, 2 quit-day, and 7 post-quit. All audio recordings were anonymized and transcribed verbatim.

Procedure

Informed consent to audio recorded sessions and having session content examined by research psychologists was obtained from the practitioner and client. Coding was conducted by two research psychologists (researcher initials: FL, CC) with previous training and experience in coding using the taxonomy. Both researchers independently coded all study materials (i.e., 2 manuals, 34 transcripts). The treatment manuals were coded into component BCTs using an established taxonomy of 43 smoking cessation BCTs with demonstrated reliability for coding service treatment manuals [4,6,24,25]. Content of treatment manuals was coded according to content pertaining to either pre-quit, quit-day, or post-quit support. Transcripts of audio-recorded behavioural support sessions were coded into component BCTs using a recently adapted taxonomy of 44 smoking cessation BCTs with demonstrated reliability for coding transcripts of audio-recorded behavioural support sessions delivered by Stop-Smoking Services [27]. This adapted taxonomy is an updated version of the original taxonomy of 43 BCTs. Adaptations included merging typically co-occurring BCTs and refining existing BCT labels and definitions [27]. The

resulting content of the taxonomies is therefore largely comparable and comprises the same BCTs.

If coders identified the same BCT within a section of text, agreement was registered. Where one coder identified a BCT and the other did not, or a different BCT was identified, disagreement was registered. If an intervention component could not be coded by a BCT label from the taxonomy, this was identified as a potential new BCT. Discrepancies were resolved through discussion or consultation with a behaviour change expert (SM).

Analyses

Inter-rater coding reliability was assessed by examining the proportion of all BCTs identified within a transcript that were identified by both coders (i.e., % positive agreement). Percentage agreement was used rather than Cohen's Kappa for numerous reasons. First, the items being coded (i.e., sentences within transcripts) were not mutually exclusive, as multiple BCTs may be present within a single sentence. Secondly, BCTs may occur multiple times within a single transcript, with coders potentially agreeing in one instance within the transcript that the BCT is present, but not in another. This does not allow a global present/absent rating for the entire transcript for each BCT. Furthermore, given the high number of 43 BCTs, the probability of selecting a particular code by chance is low. Since Kappa corrects for chance agreement amongst multiple coders, use of Kappa is likely to underestimate reliability [30].

The proportion of BCTs specified in service treatment manuals that were delivered in practice was examined according to session type rather than overall, as both services' treatment manuals had individual sections pertaining to either pre-quit, quit-day or post-quit support, and BCTs did not feature uniformly across all three sections of each manual. Fidelity of delivery for pre-quit sessions was assessed by examining the proportion of BCTs specified in the pre-quit section of the manual that were delivered in pre-quit behavioural support sessions. This was repeated for quit-day and post-quit sessions, and levels of fidelity compared across session types. These analyses were done both separately and combined across services.

The association between session duration and the proportion of manual-specified BCTs delivered with fidelity was examined by means of Pearson correlations. This analysis was done separately and combined across services.

The mean proportion of manual-specified BCTs delivered by individual practitioners across sessions was calculated for each practitioner and compared across practitioners within each service.

For each manual-specified BCT, fidelity of delivery was assessed by establishing the proportion of sessions each BCT was delivered in according to manual-specification.

This was first done according to session type then combined across session types and services, as not all BCTs featured consistently across all three sections of the manual.

The proportion of all BCTs delivered within each session that were not specified by the manual was also calculated.

Results

1. Reliability of fidelity assessment method

Mean inter-rater reliability for coding was 87.1% agreement across transcripts from both services, which is high (i.e., > 75%). Mean agreement for Service 1 was 80.9% (range 70.9% to 93.7%), and for Service 2, 93.4% (78.4% to 95.6%).

2. Overall fidelity of delivery in two NHS stop-smoking services

In Service 1, across all transcripts, the mean proportion of manual-specified BCTs delivered was 66.4% (SD 16.0; range: 38% to 90%). The average for Service 2 was 65.5% (SD 14.5; range: 35% to 85%) (Additional file 1).

3. Variation in fidelity of delivery

(i) According to session type

The number of BCTs identified in the pre-quit, quit day and post-quit sections of each service's treatment manual is provided in Table 1. A full list of BCTs identified within each section of the manual is available in Additional file 2. The mean number (%) of manual-specified BCTs delivered in each session (i.e., % fidelity) is presented according to session type, by service, in Table 1. This, alongside general session characteristics, is available for each of the 34 individual transcripts in Additional file 1.

Across both sets of transcripts, the mean proportion of manual-specified BCTs delivered per session was 66% (SD 14; range: 38% to 83%) for pre-quit sessions, 72% (SD 15.01; range: 50% to 85%) for quit-day sessions, and 62% (SD 16.4, range: 35% to 90%) for post-quit sessions (Table 1; Additional file 1).

In Service 1, fidelity was on average highest for post-quit sessions, with a mean of 69% of manual-specified BCTs delivered per post-quit session, and lowest for pre-quit sessions (mean 58%) (Table 1). In Service 2, fidelity was on average highest in quit-day sessions (mean 81%) and lowest in post-quit sessions (56%) (Table 1).

ii) As a function of session duration

Sessions lasted a mean of 15.58 minutes (SD 8.4; range: 5.01 to 36.36) and 12.39 minutes (SD 4.7; range: 5.17 to 20.17) for Service 1 and Service 2, respectively (Table 1; Additional file 1: Table S1). There was no significant correlation between session duration and the proportion of manual-specified BCTs delivered with fidelity in

Table 1 Summary of mean session characteristics and the proportion of BCTs specified in the treatment manuals delivered individual behavioural support sessions; presented by Stop-Smoking Service and according to session type

Service	Session type (No. of Transcripts)	Mean session duration (Min.Sec) (SD)	Number of BCTs in manual (according to session type)	Mean number of manual specified BCTs delivered (%) (Range)	Mean total number of BCTs delivered (SD)	Mean number of non-manual specified BCTs delivered (% of total) (Range)
Service 1	Pre-Quit (4)	28.59 (SD 5.95)	13 -	7.5 (58%) (R: 38% to 69%)	22 (SD 3.94)	14.5 (66%) (R: 47% to 75%)
Service 1	Quit-day (2)	26.41 (SD 2.72)	8 -	5 (63%) (R: 50% to 75%)	23 (SD 3.94)	18 (78%) (R: 78% to 79%)
Service 1	Post-Quit (15)	11.73 (SD 2.72)	10 -	7 (69%) (R: 40% to 90%)	19 (SD 3.94)	12 (63%) (R: 34% to 82%)
Service 2	Pre-Quit (4)	12.62 (SD 5.26)	12 -	9 (75%) (R: 67% to 83%)	23 (SD 3.55)	14 (61%) (R: 44% to 69%)
Service 2	Quit-day (2)	16.66 (SD 4.96)	21 -	17 (81%) (R: 76% to 85%)	29 (SD 2.82)	12 (41%) (R: 41% to 42%)
Service 2	Post-Quit (7)	11.04 (SD 4.33)	17 -	9.6 (56%) (R: 35% to 64%)	20 (SD 3.8)	10.4 (52%) (R: 45% to 69%)

Service 1 ($r = 0.122$, $p = 0.599$), Service 2 ($r = 0.443$, $p = 0.129$), or across both services ($r = 0.17$, $p = 0.923$).

iii) According to stop-smoking practitioner

Behavioural support sessions in Service 1 were delivered by five practitioners, each delivering on a mean of 4.2 sessions (range: 3 to 6). The mean proportion of manual-specified BCTs delivered by each practitioner was 67% (SD 9.3) across session types, ranging from 55% to 78%. (Additional file 1). Behavioural support sessions in Service 2 were delivered by four practitioners, each delivering a mean of 3.25 sessions (range: 2 to 4). On average, each practitioner delivered 67.4% (6.5) of manual-specified BCTs across session types, ranging from 58% to 74% (Additional file 1).

iv) By specific BCT

Across both services, each manual-specified BCT was delivered according to manual specification in 63% of sessions (SD: 28.5, range 0% to 100%). BCTs for which fidelity of delivery was 100% included: 'boost motivation and self-efficacy,' 'strengthen ex-smoker identity,' 'advise on avoidance of cues for smoking,' and 'information gathering and assessment.' Fidelity was lowest for BCTs: 'set graded tasks' (0%), 'prompt commitment from the client there and then' (15%), 'advise on/facilitate use of social support' (15%), and 'offer/direct towards appropriate written materials' (28%) (Table 2). The proportion of sessions in which individual manual-specified BCTs were delivered with fidelity according to session type across both services is available in Additional file 3.

4. Delivery of BCTs not included in the manual (i.e., additional content)

In Service 1, sessions contained a mean total of 21 BCTs (SD 5; range: 8 to 27), of which 12 (57%; SD 4.8; range: 3 to 21) were not manual-specified. In Service 2, sessions contained a mean of 24 BCTs in total (SD 4.6, range: 12 to 31), of which 12 (50%; SD 3.17, range: 6 to 18) were not included in the treatment manual (Table 1; Additional file 1). Across both sets of transcripts ($n = 34$), the BCTs most frequently delivered as additional content were: 'provide feedback on performance' ($n = 34$, 100%) and 'provide normative information on others' experiences' ($n = 30$, 88%) (Additional file 4).

Discussion

Behaviour change techniques delivered in practice could be reliably coded, and this could be used to assess fidelity to treatment manuals in routine clinical practice. Behavioural support delivered by two English Stop-Smoking Services contained on average 66% of the BCTs specified in service treatment manuals, indicating that a third of the recommended service content was

typically not delivered. General consensus indicates that 80% to 100% integrity to manual represents 'high' fidelity of delivery, whereas <50% represents 'low fidelity' [16,31,32]. There was substantial variability in the extent of fidelity of delivery across sessions from both services. While 32% of all sessions from both services displayed 'high fidelity,' the remaining two-thirds displayed levels of fidelity classifiable as either 'moderate' (approximately 65% fidelity) or 'low.' The levels of fidelity found in the current study reflect those obtained in similar studies assessing fidelity of delivery of behaviour change interventions in other domains [23,24] and adds to a growing body of evidence illustrating the inconsistency with which behaviour change interventions are implemented.

Variation in the degree of fidelity of delivery was observed within and across both services according to individual practitioners, session types and BCTs. For example, post-quit sessions displayed the highest levels of fidelity in Service 1, but the lowest in Service 2. Average levels of fidelity for individual practitioners varied by 23%. This may be influenced by professional backgrounds, years of experience, levels of supervision and training received, which varies substantially across practitioners in NHS Services [33]. It has not yet been established whether more experienced intervention providers have higher fidelity of delivery, but factors known to influence fidelity are provider's perceived acceptability and effectiveness of treatment [16,34]. Levels of fidelity of delivery of individual BCTs also varied substantially, from perfect fidelity (100%) to none (0%).

Session duration was not significantly associated with extent of fidelity. Insufficient time to deliver manual-specified content is therefore unlikely to be an important contributing factor for failures to deliver prescribed content in this area. However, time taken to deliver each BCT was not accounted for in analyses. It is possible that some complex BCTs, such as 'barrier identification and problem solving,' take longer to deliver than BCTs such as 'provide reassurance.' Such variation across BCTs may have in part influenced the relationship between overall observed fidelity and session duration.

This widespread variability in fidelity of delivery allows for the identification of particularly problematic areas of intervention implementation and service provision in each service. Identifying those specific practitioners, types of sessions, and individual BCTs for which fidelity is lowest allows for the establishment of specific training needs to be targeted in future training and improvement guidelines. This in turn allows for more efficient, tailored use of training and development resources, and contributes to improvements in the design and implementation of more effective interventions. Some BCTs that were included in the manual and are known to be significantly associated with improved CO-validated

Table 2 Number of behavioural support sessions in which each BCT was delivered according to manual specification across both services

BCT label	Number of sessions BCT delivered in according to manual (max 34)
1. Provide information on the consequences of smoking and smoking cessation	4/7 (57%)
2. Boost motivation and self-efficacy	2/2 (100%)
3. Provide rewards contingent on successfully stopping smoking	13/22 (59%)
4. Provide rewards contingent on effort or progress	18/22 (82%)
5. Prompt commitment from the client there and then	2/13 (15%)
6. Strengthen ex-smoker identity	2/2 (100%)
7. Identify reasons for wanting and not wanting to stop smoking	9/13 (69%)
8. Measure carbon monoxide (CO) and explain the purpose of CO monitoring	30/34 (88%)
9. Distract from motivation to engage in behaviour	1/2 (50%)
10. Facilitate barrier identification and problem solving	6/9 (67%)
11. Facilitate relapse prevention and coping	7/13 (54%)
12. Facilitate action planning/ develop treatment plan	8/12 (67%)
13. Facilitate goal setting	3/9 (33%)
14. Prompt review of set goals	15/28 (54%)
15. Prompt self-recording	4/6 (67%)
16. Advise on changing routines	2/4 (50%)
17. Advise on environmental restructuring	4/6 (67%)
18. Advise on avoidance of cues for smoking	2/2 (100%)
19. Set graded tasks	0/4 (0%)
20. Advise on stop-smoking medication	32/34 (94%)
21. Advise on/facilitate use of social support	2/13 (15%)
22. Ask about experiences of stop smoking medications that the smoker is using	22/30 (73%)
23. Give options for additional/later support	3/7 (43%)
24. Emphasize choice	2/7 (29%)
25. Build general rapport	22/23 (96%)
26. General practitioner communication approaches	13/13 (100%)
27. Explain expectations regarding treatment programme	9/10 (90%)
28. Offer/direct towards appropriate written materials	7/25 (28%)
29. Information gathering and assessment	12/12 (100%)
30. Provide reassurance	8/13 (62%)

quit outcomes [25], were delivered with low fidelity [e.g., ‘advise on changing routines’ (50%) and ‘advise on use of social support’ (15%)]. If component BCTs that are shown to be effective in research trials are to subsequently improve quit outcomes in clinical practice, health professionals delivering interventions must first adopt these BCTs routinely in practice [9].

The variations in the fidelity of delivery of the content of behavioural support found in this study represent one potential factor explaining existing variation in successful quit outcomes within and across English Stop-Smoking Services [28]. On average, half of all delivered content in both services was not manual-specified. We do not know whether delivery of these additional BCTs

adds to effectiveness of, or dilutes, the impact of the manual-specified BCTs. It certainly increases variance in the delivery of the intervention and reduces the consistency in the content of support provided across sessions. Attempts to establish associations between the content of behavioural support specified in treatment manuals and quit outcomes cannot be accurately achieved unless the additional content delivered is first identified and accounted for in analyses. A review of audit and feedback interventions found ‘additional’ BCTs present in 86% of studies examined, which in turn hampered evidence synthesis and evaluation [35]. In the present study, of the additionally delivered BCTs, some featured consistently in all sessions despite not being prescribed in either service’s

manual (e.g., 'provide feedback on performance'), and others such as 'boost motivation and self-efficacy' have been shown to be effective [25]. It is possible that practitioners recognize the value of these BCTs, or that they are easier to deliver routinely or intuitively. If research evidence suggests such BCTs contribute to treatment success, they should be considered for inclusion in treatment manuals.

The taxonomy of smoking cessation BCTs demonstrated high reliability when applied to coding treatment manuals and session transcripts. It provided a consistent, common language by which to compare the content of manuals and sessions, and in turn quantify fidelity of delivery. The taxonomy therefore represents a suitable, systematic method by which the fidelity of smoking cessation behavioural support interventions may be assessed. It has been shown that novice coders may be reliably trained to code the content of treatment manuals and session transcripts using the taxonomy [27]. The taxonomy may therefore serve as a potentially feasible tool for service monitoring and evaluation. Taxonomies are available for other health behaviours, such as physical activity and healthy eating [36], alcohol use [37]; and a comprehensive non-behaviour specific taxonomy of BCTs is currently being developed [38]. Whether these taxonomies may be applied as tools for assessing fidelity of delivery of behaviour change interventions in these other behavioural domains is yet to be established.

This study raises the issue of the extent to which treatment manuals are fit for purpose. The evidence base for the BCTs in the services' manuals was not assessed, nor was the extent to which manuals are clearly written and conform to training standards and national guidelines. This is not only necessary for interpreting results of fidelity assessments but also for comparing the quality of services provided, since both the planned content and the extent to which content is delivered are essential aspects of assessing the quality and hence likely impact of a service. For instance, the post-quit sessions delivered in Service 2 had an average lower percentage fidelity (56%) than those delivered in Service 1 (69%). However, the post-quit manual from Service 2 contained more BCTs (17) than that from Service 1 (10). The mean number of BCTs delivered per post-quit session in Service 2 was higher than that in Service 1 (approximately 10 vs. approximately 7 BCTs, respectively). Therefore, although fidelity appears to be poorer in Service 2, the post-quit sessions may in fact have potentially been more effective in helping clients successfully quit, as a higher number of techniques were delivered. This raises the question as to whether 100% fidelity is necessary to produce desired treatment outcomes [16]. Combining an analysis of the extent to which manuals are based on good evidence with an assessment of fidelity will give a more comprehensive

assessment of delivery and stronger evidence of intervention quality than considering either evidence or fidelity on its own.

The question of whether 100% fidelity of intervention delivery is a desirable aim is under debate [16]. Strict adherence to treatment manuals may be detrimental to therapeutic interactions, as not all content specified in manuals will be relevant to all the individual needs and concerns of intervention recipients [39,40]. The delivery of additional, non-manual specified BCTs may be one means by which practitioners are tailoring the content of support provided to client needs and are increasing flexibility in their practice. Furthermore, the manuals from both services contained a high number of BCTs, which may not always be feasible or appropriate to deliver in practice. However, manuals are essential to maintaining a degree of consistency and standards in service provision. Some argue in favour of a middle ground in which core, prescribed intervention components are delivered with a degree of additional flexibility and tailoring in how content is provided. Such an approach does not compromise fundamental treatment integrity, and offers a potentially more feasible, realistic and beneficial model of treatment delivery [16,40].

Limitations of the current study firstly include the sample size of only two services, which means that these findings may not reflect all sessions delivered by practitioners, other services or behavioural support provided in contexts other than the English Stop-Smoking Services. In addition to assessing fidelity in terms of presence or absence of BCTs, it would be a step forward to establish a method for also assessing the quality with which BCTs are delivered. An additional key question is whether fidelity is associated with quit outcomes. Interventions implemented with higher levels of treatment fidelity have been shown to be associated with better treatment outcomes than those with poor fidelity in other areas [41]. However, the presently examined sample of services had high and average success rates respectively but similar levels of fidelity; the extent to which differences in fidelity may help explain variance in quit outcomes needs to be examined in future research with a representative sample. Audio recording was used rather than video recording, as it is less intrusive, more feasible and economical. Since all BCTs in the taxonomy require some degree of verbalisation (e.g., 'advise on,' 'facilitate,' 'offer'), video recording is unlikely to substantially add information in terms of content delivered. Since video recording is more intrusive, it is more likely to interfere with routine practice as a result of social desirability or demand characteristics. Nonetheless, practitioners were aware that their sessions were being audio recorded and may thus have been susceptible to demand characteristics and attempted to improve their practice under

observation. Therefore, these sessions may not be representative of typical practice. However, these sessions are likely to represent a 'best case scenario,' and therefore over-estimate rather than under-estimate fidelity of delivery.

Conclusions

The degree to which smoking cessation behavioural support interventions are implemented in routine clinical practice according to manual specifications can be reliably assessed. A preliminary analysis of service delivery in two English Stop-Smoking services demonstrated that manual-specified content, including numerous evidence-based BCTs, was not implemented with high fidelity. Manuals represent one potential tool for bridging the gap between evidence-base and practice in the implementation chain, as does training to implement those manuals. The present findings underline the general need to establish routine procedures for monitoring the fidelity with which behaviour change interventions are implemented in clinical practice, with a view to improving them where they are found short.

Additional files

Additional file 1: Session characteristics and the proportion of BCTs specified in the treatment manuals delivered individual behavioural support sessions; presented by Stop Smoking Service and according to session type. This table presents the session characteristics (i.e. duration, type) and the number of BCTs delivered with fidelity in each individual session.

Additional file 2: BCTs included in the treatment manual from each Stop Smoking Service. This table lists the BCTs identified in each session of the treatment manual from both services.

Additional file 3: Proportion of behavioural support sessions each manual-specified BCT was delivered in according to session type (pre-quit, quit-day, post-quit), presented combined for both services. This table presents the proportion of each type of session each manual-specified BCT was delivered in with fidelity.

Additional file 4: Non-manual specified BCTs delivered in behavioural support sessions, presented according to session type and ranked according to frequency of transcripts featured in. This table lists, in order of frequency, the BCTs most often delivered as additional, non-manual specified content, in sessions.

Abbreviations

BCT: Behaviour change technique; CO: Carbon-monoxide; NHS: National Health Service; NCSCCT: National Centre for Smoking Cessation and Training.

Competing interests

FL has received travel funds and hospitality from Pfizer, who manufacture Champix. RW has undertaken research and consultancy for companies that develop and manufacture smoking cessation medications. RW has a share of a patent in a novel nicotine delivery device. SM has received travel funds and hospitality from Pfizer, who manufacture Champix. She has received fees for speaking at educational events sponsored by Pfizer. She has received research funds and consultancy payments from the Department of Health and the Department of Transport. CC declares no competing interests.

Authors' contributions

FL, SM, and RW conceived the study. FL and CC collected the audio recordings, transcripts, and service manuals and conducted preliminary analysis and coding of data. All authors participated in interpretation of the

results. FL drafted the write-up, with input by SM and RW on subsequent drafts. All authors read and approved the final manuscript.

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