Feasibility and acceptability evaluation of the PRIDE (Promoting Independence in Dementia) intervention for living well with dementia

Running Title: PRIDE Feasibility Study

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ABSTRACT

Objectives: Post diagnostic psychosocial interventions could play an important role in supporting people with mild dementia to remain independent and at home for longer. The PRIDE intervention was developed to address this. We tested the feasibility and acceptability of this intervention.

Method: This mixed methods non-randomized, pre-post feasibility study was carried out at four sites across England. Facilitators were recruited from the voluntary sector and memory services. Participants with dementia and their supporters took part in the 3-session facilitator led intervention. Outcome measures were collected at baseline and at follow up. To evaluate acceptability, focus groups and individual interviews were conducted with a sub-sample of participants after follow-up outcome measures had been collected.

Results: Thirty four dyads consented to be in the study over a recruitment period of ten months, with 14 facilitators providing the intervention. Seventy-nine percent of dyads took part in at least two sessions, and 73% in all three. Outcome measures were completed by 79% of participants without difficulty, and with minimal missing data. No significant changes were found on pre and post assessments, but post-hoc analysis found moderate effect size improvements for self-management in people with dementia (d=0 .41) and quality of life in carers (d=0.40). Qualitative data indicated that dyads found the intervention acceptable, as did intervention facilitators.

Conclusions: This psychosocial intervention, designed to assist people with dementia to maintain independence through social, cognitive and physical activity, was successfully delivered and evaluated. The intervention and most outcome measures were both acceptable and feasible. This study provides important data on recruitment rates and outcome measurement for a future definitive randomized controlled trial, to evaluate the effectiveness of the PRIDE intervention.

Keywords: Dementia, Psychosocial Intervention, Research Design and Methodology, Community Care

INTRODUCTION

The EU Joint Programme for Neurodegenerative Disease Research and the UK government have highlighted the need for the development of high quality specialist services, in particular psychosocial interventions, to support the growing needs of people with dementia (DOH, 2016). People with dementia may reduce their activities due to perceived stigma, neurodegenerative decline, loss of autonomy and self-confidence (Birt et al., 2017; Lion et al., 2019). Furthermore, family and friends may also inadvertently contribute to a reduced sense of self-determination(Sterin,2002). Given the risk of 'prescribed disengagement' at the time of diagnosis(Low et al., 2018), counteracting this soon after diagnosis may facilitate better adjustment and ongoing management of dementia (Burgener et al., 2009). This in turn may enhance independence and social inclusion and delay residential home placement (Clarke et al., 2103).

The Promoting Independence in Dementia (PRIDE) programme seeks to address this. Our intervention drew on interconnecting strands of the overall PRIDE project, such as epidemiological and qualitative data, and PPI involvement (Csipke et al., 2018; Yates et al., 2019). [9] It included work from the English Longitudinal Study of Aging (ELSA; Steptoe et al., 2013)[10] cohort study which found that loneliness was linked to cognitive decline, although social isolation in itself was not Rafnsson et al., 2017) and those with close social networks had a reduced risk of cognitive decline (Khondoker et al., 2017). Furthermore, we found that computer use and physical activity were associated with both a lower risk and progression of dementia (d'Orsi et al., 2017; Soni et al., 2017;Stock et al., 2015). A critique of literature about social participation highlighted challenges associated with memory loss, social relationships and social structures in enabling people with dementia to remain independent (Birt et al., 2019). Unlike many such interventions, stakeholders (persons with dementia, carers and older people) contributed to shaping the intervention(Yates et al., 2019).

The Medical Research Council recommends that uncertainties associated with conducting a large scale study can be addressed in feasibility work (Craig et al., 2008). Our aims were therefore to examine the feasibility of the PRIDE intervention by investigating: recruitment and retention rates across sites; engagement of intervention providers and participants; the acceptability of the PRIDE intervention; and acceptability of outcome measures.

METHOD

Design

This is a mixed methods feasibility study of the PRIDE intervention (see protocol; Csipke et al., 2018)[8]). Outcome measures were collected at baseline and post-intervention delivery, to test feasibility of use with participants and to inform the design and methods for a future large scale study. A sub-sample took part in interviews/focus groups following the intervention, to examine acceptability and engagement with PRIDE.

Participants

Participants were adults (18+) who were able to read and communicate verbally in English and had the capacity to give informed consent in accordance with the Mental Capacity Act(DCA, 2005).

Persons with dementia were community dwelling with a dementia-diagnosis and with mild dementia as defined by 0.5-1 on the Clinical Dementia Rating (CDR) Scale (Morris, 1993). They were expected to have a supporter (family member or friend) willing to participate with them. Supporters were included since although the intervention focussed on those with dementia, many of the concepts of

PRIDE (eg, decision making, communication skills) take place within a social context. The term 'supporter' was used throughout since it denotes support as part of reciprocity within a relationship, rather than the term 'carer' which implies dependence.

Supporters were eligible if they were in regular unpaid contact with the person with dementia (minimum three hours a week).

Intervention Facilitators were either voluntary sector staff working as 'Dementia Advisor Workers (DAWs)' who provided information, advice and support, alongside or within memory clinics, or health and research staff working with memory services.

Sample size and sites

Sample size calculations were not made. Instead we planned to use sites that were geographically varied to explore recruitment across diverse settings. We aimed to recruit up to five sites across England, with approximately ten dyads at each site. This would provide sufficient data to evaluate recruitment and retention rates, time required to recruit dyads, whether the participants and facilitators found the intervention to be acceptable and to test outcome measures. Sites were eligible if they had local researchers to undertake the baseline and follow-up measures; could provide a supervising clinician acting as a principal investigator; and had access to dementia facilitators to deliver the intervention. We provided site-based researchers with training in screening, measure completion and all study procedures.

Procedures

Recruitment was through NHS memory services, Join Dementia Research (a national register of people interested in taking part in dementia research), and voluntary sector organisations. Potential participants were approached and given study information. If they agreed to participate, researchers arranged to obtain written informed consent and complete baseline measures. Dyads were linked with local intervention facilitators who would then meet with the dyad on three occasions, approximately four weeks apart. After the final session, follow-up outcome measures were completed.

Referral sources, along with reasons for ineligibility and retention rates were recorded. Additional support such as telephone calls or requests for extra sessions were recorded. Additional support required by research sites and intervention facilitators such as site visits and further training were also recorded.

Ethics

The study was approved by the East Midlands Nottingham 1 Research Ethics Committee (16/EM/0044). Participants were fully informed of potential risks and benefits and that they would be free to withdraw at any time without affecting their care. Participants with mild dementia were expected to have capacity to provide consent for themselves (Csipke et al., 2018). In addition to providing consent at the start of the study, researchers were aware of the need to regularly check participants understanding of the research process. The study also obtained Health Research Authority (HRA; https://www.hra.nhs.uk/approvals-amendments/) approval via the sponsoring university for governance and legal compliance required for NHS sites to carry out studies. Safety procedures for researchers in the UK followed standard guidelines. Reporting procedures for serious adverse events(s) were in place at all sites.

The PRIDE intervention

The intervention is delivered by a facilitator in three, 60-90 minute sessions. The intervention aims to equip the person to participate in activities, build on communication skills and to enable them to continue making choices during the course of their dementia. In between sessions the person is encouraged to engage in activities that will support their independence, social inclusion, and engagement in the community. A paper-based workbook with space for written records supports usage in and between Yates et al., 2019).

Acceptability of intervention - qualitative evaluation

Qualitative data were audio recorded and transcribed. Framework analysis of focus groups and interviews with a convenience sample of participants was planned to: (1) explore if participants found the intervention/study procedures suitable and feasible, and (2) obtain their views on taking part. Intervention facilitators were also asked to take part to obtain their views of the intervention. Focus groups and in-depth interviews provide an opportunity for new perspectives on experiences to develop as participants discuss and challenge each other's views (Jenson and Laurie, 2016).[20] Interview topic guides were created, see Tables 1 and 2.

-Insert Tables 1 & 2 here-

Outcome

The *Clinical Dementia Rating (CDR; Morris, 1993*) was used to check that participants had a score of 0.5-1 (mild dementia).

Researchers read instrument questions out to participants to ensure consistency and promote inclusiveness for those who found reading text difficult. During this time, supporters were asked to complete the self-report questionnaires. Measures were chosen to assess the PRIDE intervention concepts and goals.

For people with dementia the included measures reflected the core of the intervention such as: self-management (the *SMAS-30; Schuurman et al., 2005*); independence (the *CASP-19; Hyde et al., 2003*); engagement and independence (the *Engagement and Independence in Dementia Questionnaire – EID; Stoner et al., 2017*); and the IPA(Hammar et al., 2014) measuring self-determination and participation; hope and resilience (the *Positive Psychology Outcome Measure*- PPOM; Stoner et al., 2017); and loneliness/social support (the *ELSA three-item social support questions* taken from the revised version of the UCLA Loneliness Scale; Hughes et al 2014) Measures also included activities of daily living (*The Bristol Activities of Daily Living Scale – BADLS; Bucks et al., 1996*; rated by the supporter), cognitive function (*Standardized Mini-Mental State Examination (SMMS;E; Vertesti et al., 2001* and the *Hopkins Verbal Fluency and Learning* Test; Brandt, 1991[28]) functional mobility (*Timed Up and Go test - TUG; Podsiadlo and Richardson, 1991*), quality of life (*Dementia Quality of Life measure – DEMQOL; Smith et al., 2005*; *Health-related quality of life - EQ-5D; Euroqol Group, 1990*) and economics in relation to wellbeing (the *Icecap capability measure for older people - ICECAP-O; Coast et al., 2008*; and the *Client Services Receipt Inventory - CSRI*[3]) used for measuring service costs. The *CSRI* was included to examine acceptability of its use by participants, so no analysis was planned for this study.

Supporters completed self-report measures as follows: the quality of life *EQ-5D (Euroquol Group, 1990)* and the well-being measure *ICECAP-O (Coast et al., 2008).*

Intervention providers and participants were asked to complete fidelity checklists after each visit to examine adherence to the intervention. Details of this are reported elsewhere (Walton, 2018).

Analyses

Quantitative

Researchers completed measures with participants, and any difficulties this were noted. Missing data was examined for patterns of non-completion. Multiple imputations with a linear regression were conducted for scale variables at baseline and post intervention to impute missing variables. Basic pre-post t-tests, followed by post hoc analyses were carried out when differences in means warranted this.

Researchers completed measures with participants, and difficulties were noted. Basic pre-post t-tests were run when data had a normal distribution, otherwise non- parametric Wilcoxon rank tests were used. Further post hoc analyses were carried out when differences in means warranted this.

Qualitative

Qualitative data were audio recorded and transcribed. Framework analysis enables an evaluation of applied interventions (Srivastava and Thompson, 2009). The analytical steps are: familiarisation with the data, generating initial codes which reflect the research questions in topic guides, producing a thematic framework, index charting and mapping of data which enables reflection on differences and similarities in experiences of the stakeholder and also interpretation and presentation of

themes. Findings were explored to see if there were differences in the experiences of people with dementia, supporters or intervention facilitators, as this would add further understandings of the intervention in the real world.

RESULTS

Site Recruitment and Set up

Six NHS Foundation Trusts with memory services expressed an interest in participating in the study. Two sites withdrew as they were unable to identify both researchers and intervention facilitators. All participating sites were predominantly urban. Each site was provided with a site set-up visit lasting 2-3 hours, which included training and information covering participant identification/screening/consenting, and measure administration. Sites were also given instruction in study procedures such as communications with the research team, data collection and entry, and documentation and site files.

Obstacles to implementing the study

The final sample was smaller than initially planned due to restructuring of national NHS research governance processes, and associated delays of 10 months to set-up of the study which also contributed to the withdrawal of the two sites from the study. The rate of recruitment was also slow, taking 10 months to recruit 34 dyads. A third obstacle related to changes in the facilitator workforce where availability of DAWs which fluctuated on an annual basis according to local commissioning arrangements. For example the aforementioned delays in national governance procedures resulted in intervention facilitators from the voluntary sector who had been willing to engage in intervention delivery, now no longer in post 10 months later; legal agreement with one of

voluntary organisations was very time consuming with head office delays impacting on availability of staff to deliver the intervention; where DAWs were available and engaged the NHS site withdrew from the study; and many DAWs were unable to add to their workload to deliver this intervention even when remuneration for time and training was offered. We overcame obstacles to engaging intervention facilitators by working with NHS research departments at each site and their clinical service managers to nominate intervention deliverers from their memory services.

Dyad recruitment

One hundred and fifteen potential participants were identified across the four participating sites. The JDR register provided 61 potential participants, the voluntary sector five, 23 participants taking part in other studies expressed an interest, while memory clinics referred 25, and one was referred by a psychiatrist.

Of these, 23 (20%) were uncontactable, and 23 (20%) were out of the catchment areas, seven (6%) were not clinically eligible, 14 (12%) were not eligible for other reasons. Of the 48 who were eligible, 14 (41%) declined to take part, leaving 34 dyads recruited to the study. Recruitment ended at ten months, to allow for time for intervention delivery and for follow ups to be completed.

The mean age of participants was 77.67 (SD= 9.07) and 23 (67%) were men. Thirty (88%) were White British and four (12%) were of another ethnicity. Half of participants were diagnosed with Alzheimer's disease, six (18%) had mixed dementia, four (12%) vascular dementias and the remaining seven (8%) had an unknown dementia diagnosis. Twenty seven (79%) supporters were

women, with an average age of 69.18 (SD=11.89). Thirty two (94%) were White British, and two (6%) were of other ethnicity.

The flowchart of study recruitment and retention is shown in Figure 1.

- Insert Figure 1 here –

Four participant/supporter dyads (4 men with dementia; 4 spousal supporters) were recruited to a focus group, at two sites, three intervention facilitators (all women) agreed to take part in a focus groups. Individual telephone interviews were conducted at two sites with two participants and two supporters at each site. These were four men with dementia and four women supporters.

Twenty-six health professionals from voluntary organisations and NHS teams registered for and completed the training programme, with sessions delivered at each site. Managers and staff not planning to deliver the intervention were invited to attend to: enhance support during the study; maximize interaction opportunities between different teams and; build relationships during the training itself. Eleven (43%) were voluntary sector staff, seven (27%) dementia researchers, four (15%) dementia nurses, and four (15%) allied health professionals. Fifty four percent of those who took part delivered the PRIDE intervention. The remaining 12 trainees (46%; all voluntary sector) did not deliver the intervention due to high workloads, were managers attending the training for information purposes only, or were staff who were shortly to leave their organisations.

Intervention Delivery and Uptake

Of 34 dyads consenting, 33 took part in the first session. Subsequently, seven withdrew; one due to ill health, one the supporter's ill health, one due to the facilitatordrop out, and four gave no reason. Of these, 26 (79%) took part in two sessions, and 24 (73%) in all three sessions, none requested an

extra session. Five took up the offer of telephone contact, with eight calls taking place. Calls took 5-15 minutes and involved updates from the participants about their activities.

One site reported three SAE's (hospital treatment for a medical condition unrelated to PRIDE).

Site and intervention providers were offered support from the study team as required and newsletters updating on progress were sent to each site on two occasions. The study team offered additional site visits if required, but only one site took up this offer. All sites had on-going questions about procedural issues which were resolved via telephone or email.

Measure Performance

Of those who consented to take part, all 34 participants completed the baseline assessment and 27 (79%) completed follow up assessment

Outcome Measures

Measures were completed without significant difficulty, despite the numerous instruments used, including the lengthy CSRI. Data collection took approximately 1-2 hours, and all were completed in a single session. There were particular challenges associated with the *TUG* measure of gait, which involved walking across a room in straight line: some participants' homes did not have sufficient trip-free space – although solutions were found in all cases. None of the measures caused distress.

There were no measures or specific items with enough missing data to warrant concern, and overall less than 2% of data was missing, over both time points, for both participants and supporters.

Exploratory t-tests (baseline versus follow up) were carried out as per study protocol. No significant differences were found, although the *SMMSE* approached significance at p=0.05 (Table 3 and 4). Post hoc analysis found that the *SMAS* had a moderate effect size (d) of 0.41 indicating that self-management scores for people with dementia improved. In addition, the EQ5D-VAS for supporters indicated a moderate effect size (d = 0.40) indicating that well-being scores improved. There were no differences in cognitive test performance but the SMMSE decreased over time.

Based on post hoc exploration (effect sizes; Cohen's D), further analysis of *SMAS* scores were carried out taking into consideration engagement (from fidelity checklist) with the intervention. In this analysis, only scores on enactment (doing what was planned in the session) were used. Scores were converted into categories of ≤75% or 76-100% with enactment based on the distribution. *SMAS* means were calculated for the two categories (with an added 'unknown' group of participants who did not complete the checklists) at baselines and follow up. Those with higher engagement scores demonstrated better self-management abilities at baseline, which remained true at follow up (no change in scores). The group with lower engagement also had the lower baseline self-management scores, but by the end of the intervention at follow up these matched the first group (Table 5).

-Tables 3, 4 & 5 here-

Qualitative findings

Three themes emerged from the qualitative analysis: understanding the ethos of the PRIDE intervention; relationships within the PRIDE intervention and the relevance of the PRIDE intervention.

Understanding the PRIDE study ethos

Participants were able to articulate the ethos of the PRIDE intervention as being that of enabling people with dementia to maintain some independence. The sense of hope instilled through the intervention was captured by a facilitator who stated:

> *It's for maintaining independence, isn't it, and it's ensuring that people are constantly putting things in place to make sure that they live happy, independent and active lives… to stay in control of their lives (Facilitator 2)*

People with dementia and their supporters spoke of the confidence they gained through being part of the PRIDE intervention.

> *thought it was very good. [filling in manual] It gives everybody, erm… can't think of the word… researchers and everybody knows what I'm doing and how I'm thinking. I thought that was good, anyway. (Person with dementia 3)*

Facilitators helped participants engage, for example where a person with dementia found it difficult to communicate, use of a singing video helped her relax and the facilitator noted:

> *she held my hand and said thank you, she was understanding that we were adapting it not to make her feel threatened or anything like that but to do it to the way that she enjoyed … so that she could still take part in everything (Facilitator 3)*

Relationships within the PRIDE intervention

Facilitators worked face-to-face through the manual and activities with the participants and helped set priorities and action plans. All people spoke of this personal contact as important:

> *The best benefit we got was actually talking to the people that came out. I think that made a lot of difference, person to person. (Supporter 2)*

Both facilitators and supporters acknowledged the essential role the supporter played in encouraging the person with dementia to engage in the intervention. This might have been helping the person with dementia engage in intervention plans in practical ways such as getting equipment and keeping action plans up to date.

> *I think he was definitely prompting her to do the knitting and he went out to the shops and bought the wool with her, and... so yeah, and all the sheets that were filled in, he filled those in for her. But she did it all, she was doing all the activity (Facilitator 1)*

However, one facilitator explained how they had had to manage a supporter who wanted to take the lead:

> *The partner will want to take the lead and speak for the person; we had to change it a little bit just to say please could they [person with dementia] go first and express their feelings (Facilitator 3)*

Not all people with dementia had active support from their family; this was reported as being due to poor *health of the supporter or limited interested from the wider family.*

> *'I was not able to reach him [the son], so I do not know how aware he was of what we were trying to achieve.' (Facilitator 1)*

Relevance of the PRIDE intervention

PRIDE was aimed at those with mild dementia and all thought the intervention would be most useful soon after diagnosis. This support explained it helped to reduce fear following a diagnosis:

> *We wouldn't have known where to go and that actually you can have some sort of life, because when something like that is said to you, you think that's the end. That's actually where the fear comes because really don't know where to turn or what to do and somebody coming in and talking to you about it and helping with these sort of things gives you a vision. (Supporter 4)*

> *I think it's good just being diagnosed because it gives you a look into what help you can get and things like that (Person with dementia 2)*

A facilitator confirmed that the PRIDE intervention would give hope to those newly diagnosed with dementia:

> *I feel that they're trying to recognize somebody that's newly diagnosed, to actually state that because you have a diagnosis, it doesn't mean that life stops. (Facilitator 3)*

This contrasted with the other dyads where the person had been living with dementia over 12 months. Here facilitators found it most challenging when they were delivering the intervention to 'socially active' couples. However, it was also recognized that PRIDE may be suitable to lay the foundations of skills that may be useful as dementia progresses:

> *Because I do think the lady maybe she is at risk of maybe losing some of those activities' (Facilitator 3).*

The intervention delivery was centred on the PRIDE manual. While the majority found the manual easy to use there were some negative comments on layout and the use of smiley faces:

'If you don't mind me saying, I think this is a kiddie's way of doing this.' (Person with dementia 3).

The facilitators used the manual in every session. However, they all gave examples of how they had had to adapt the delivery; often this was due to over enthusiasm:

> *On one occasion I had to scrap everything and pull it right back, because we thought too big, it is good experience (Facilitator 1).*

Discussion

Overall, the intervention and training was feasible to deliver and was well received by those who took part. Of those eligible 59% consented to be in the study. Seventy-nine percent attended at least two sessions, and 73% attended all three. Setting up sites to be ready to provide the intervention had its challenges, but these were overcome. The strength of this study is that we have good data on the required time to recruit participants; that intervention delivery is best developed and organized by the recruiting research site since when research teams attempt collaboration across agencies, fluctuating commissioning arrangements can undermine the progress of applied research such as this; and some outcome measures such as the *TUG test* may not be flexible enough for this type of study.

Recruiting, sites as well as participants, is one of the common challenges of health research, but also the key to their success (Borschmann et al., 2014; Kaur, Smyth and Williamson, 2012; Nuno et al., 2017). Estimating adequate recruitment timelines for a large trial is one of the key functions of a feasibility study (Thabane et al., 2010). We found two significant obstacles. The changes in the NHS governance approval system was beyond the team's control and unexpected, especially as we had completed a similar procedure some months prior. Secondly, matching available intervention facilitators to research sites was difficult. The feasibility study required the recruitment of sites that not only had the capacity to identify, recruit and assess participants, but to also have available

suitably qualified staff to provide the intervention. Initially, it was envisaged that Dementia Advisors from voluntary organisations would be able to fulfil this role. Although the project had the support of the head and regional offices of these voluntary organisations we found that it was untenable to rely solely on the voluntary sector. Attrition due to organisational factors and delays in participants recruitment have been found in other studies relying on interventions being delivered by the voluntary sector (Mountain et al., 2017) and although our intervention providers were paid employees, similar issues arose. Therefore, NHS staff working with memory clinics, typically nursing staff and clinical dementia researchers were approached to facilitate the intervention. This observation suggests that a wide variety of staff can deliver an intervention of this type. Furthermore, we have now developed more specific site-requirements when engaging sites on the upcoming larger scale project(Shafayat et al 2019). Ellwood and colleagues(2018) also found that a targeted approach to site recruitment (in their case, care homes) was more successful and less time consuming than a broad approach.

Fewer participants than anticipated were recruited, due to the difficulties encountered with site and interventionist recruitment start dates. However, we continued with the study for 10 months until we had enough information to guide us when planning a large trial. Recruitment via the JDR register was not successful for the following reasons: some potential participants were not aligned adequately to the research sites and many did not respond to our attempts to engage them. Recruiting from memory clinics was the most successful method of recruitment. Ill-health was a common cause for not continuing with the study and four dyads withdrew from the study without giving a reason. Of those who remained in the study, compliance with the three intervention sessions was high.

All measures were acceptable to participants with only minor difficulties encountered. The *TUG* test occasionally required moving obstacles out of the way, but this was surmountable. Although there was some missing data, it was minimal (i.e. less than 2%). Although moderately lengthy 1-2 hours, all assessments were completed in one visit and no participants were distressed by the questions. With this limited sample, differences between groups were not expected, and were just looked at for exploratory purposes. Based on the results here, the authors conclude most of these measures would be suitable for the main trial.

Participant and facilitator qualitative perceptions of the PRIDE intervention

The convenience sample was small representing only 11% of the dyads recruited, however there was consistency in the accounts provided. All found the intervention acceptable and reported positive experiences. The timing of the intervention is an important factor with most relevance being with those newly diagnosed. Supporters and facilitators encouraged the person with dementia to act and reflect on activities and tasks. Having a facilitator seems to have empowered the person with dementia to be actively involved in the intervention. This maximized the ethos of the PRIDE study and contrasts with previous research where there have been reports of family members trying to do more than is necessary or needed, for or on behalf of, the person with dementia (Sterin, 2002).

The personal interactions with the facilitator were reported as important, possibly reflecting a therapeutic alliance. Caution is needed as it is important to differentiate whether positive outcome scores are due to the intervention or the therapeutic alliance between dyad and facilitator. This is especially important to explore as participants consistently reported that they did not use the manual between sessions. A large scale trail should develop methods to explore this observation.

Limitations

The main limitation to this study is that we were unable within our timescale to engage that range of sites planned to explore geographical and participant variability. A future study may need to stratify for geographical location. The present study demonstrated that a variety of dementia staff of differing grades and training can successfully deliver this intervention, but we have not calculated the costs of training and time taken to deliver the intervention.

Clinical and Research Implications

Looking further into the mean differences in self-management (*SMAS*) scores, the moderate effect size suggests that with a larger sample significant differences are possible. These findings suggest that not only might the intervention be beneficial in improving self-management, but also that this could be especially true for those who would gain the most benefit from the intervention. Self-management skills, as measured by the *SMAS*, and the confidence to use these skills can be a key asset to limit the excess disability often found to have a significant impact on dementia (Brody et al., 1971; Spector and Orrell, 2010). Given the concept of the PRIDE intervention and its potential for empowering people with mild dementia to live well, these preliminary findings suggest that the *SMAS* self-management instrument has good potential as a primary outcome measure in a future large scale trial. Larger sample sizes might also be able to detect a change in cognitive performance associated with this intervention.

Conclusions

The PRIDE intervention was feasible to carry out and acceptable to persons with dementia and their supporters. Our findings provide good information on recruitment and retention rates and the time taken to recruit 34 dyads across four sites. Involving memory clinic staff as intervention facilitators had a positive impact on overcoming some of the delays encountered. Examination of the

performance of outcome measures suggests that most were acceptable and feasible to use, but there may be scope to exclude some of the instruments use in a future study. The self-management instrument shows the strongest promise and is in line with the concepts underlying PRIDE. The findings of this feasibility study can be used to inform a future large scale randomized controlled trial of the PRIDE intervention.

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Authors' contributions
MO, EMC, GC, EH, and GM developed the original concept of the study. All authors drafted the original protocol, developed the design and methodology and contributed to the development of the PRIDE intervention and manual. EC drafted the paper and is the main author. All authors reviewed and commented on drafts of this paper. All authors read and approved the final manuscript.

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Table 1 Topic guide for focus groups with participants and supporters

Stem Questions and Prompts
1) What did you think of the PRIDE manual? - Is there anything you like about the manual? Why? - Is there anything you dislike about the manual? Why? - Which topics did you choose to work on? Why? - Were any of the sections / topics in the manual particularly useful to you? Why? - Were any of the sections / topics in the manual ***not*** useful or relevant to you? Why? - What do you think about the resources provided for the topics you chose?
2) What did you think of the following exercise? - PRIDE profile: information about you (p6-7) - Finding a balance grid (p8) - People and connections bubbles (p12) - People and connections support network map (p14) - Making decisions: How do you make decisions? (p42) - Getting your message across: Supportive relationships (p58) - Do you have any suggested changes for these exercises?
3) What did you think of the clarity of information/language used/layout and design? - How well were you able to follow the manual? (eg finding the right page) - Were you able to understand the information presented in the manual? (eg appropriate language used, non academic terms) - What do you think about the layout of information? (eg any issues with clarity, size of text, presentation of information?) - What do you think of the design of the manual? (eg color, images)
4) What do you think about the intervention/programme? - Was the programme useful? (eg If yes, in what ways? If no, why not? How could the programme have been more helpful for you?) - Did you make any changes to your activities/lifestyle/actions related to taking part in this programme? If so, what changes did you make? Why? If not, why not? - How was your experience of working with a dementia advisor? - Was three sessions too many, too few, or just right for this programme? - How long did your sessions tend to take? Was this too long, too short, or just right? (If too long or short – recommend a suitable amount of time)
5) What did you think of the plan, do, review section? - Did you find planning activities and actions helped you to actually go and do them? - How did you find keeping track of your activities/actions? (eg Useful? Time-consuming?) - What do you think about reviewing your activities/actions in sessions 2 & 3 with your advice worker? (eg Useful? Meaningful?) - What do you think about the worksheets?
6) Did you use support? - Did you need any support to do the programme? (eg, How often? What kinds of support?) - Were you satisfied with the support you received while you were taking part in the intervention?
7) Did you experience any challenges? - Did you have any problems with the programme? If so, how did you overcome these?
8) Experience of PRIDE. - Thinking about your experience on this project, what went well? - Was there anything that didn't go so well? (eg anything you were not satisfied with)

Table 2. Topic guide intervention providers and delivered the PRIDE Intervention.

Stem Questions and Prompts
1) Please can you tell me about your experience of working with people with dementia?
2) How have you found the experience of delivering the PRIDE intervention? - How difficult or easy is it to deliver the intervention? - Why?
3) How helpful was the training in enabling you to deliver the PRIDE intervention? - What was most helpful? - What was least helpful?
4) Now that you have delivered the intervention is there anything you would change about the training? - Manual - Content - Style of delivery
5) **How did you make contact with participants prior to starting the intervention?** - Who gave you information? - What about type of information you had about participants? - How long between getting information and starting intervention? - Where there any barriers to starting the intervention
6) To what degree were the skills and knowledge taught in training useful for delivering the Intervention? - Practical skill? - Theoretical knowledge ?
7) Did you use the DAW training manual alongside the PRIDE manual? - If so, did how did this work? - If not, why not?
8) **Which parts of the DAW training manual are most useful when delivering intervention session**
9) Which part of the DAW training manual might need to change? - If so, what changes would you make? Eg omitting content (and what?), adding content (and what?)
10) Have you experienced any barriers to applying what you learned in training to the Intervention? - Resource - Understanding - Links between training and intervention delivery
11) For you, what was the most important part of the intervention? - Why was that most important?
12) For you, what was the least helpful or important part of delivering the intervention, and why? - Why was that least helpful or important in your view? - How would you change it?
13) Which part of the intervention do you think participants most benefited from, and why? - In what ways did they benefit? - Did participants report benefits or is this based on your observations?
14) Which part of the intervention do you think participants least benefited from and why? - In what way?
15) What did you think of the PRIDE manual? - Was the language easy to understand? - How easy was it to navigate between sections? - What did you think of the case stories?
16) What did you think of the additional resources? For example the 'do' and the 'review' worksheet? - How did you use them? - What, if anything, would you change?
17) How do you feel about your ability to deliver the intervention? - What would help you feel more confident about your ability to deliver PRIDE as planned?

18) **How do you feel about the time you had to deliver the Intervention?** - Where there other time constraints? - Did participants need/use three sessions?
19) Would you recommend others do the DAW training? - If yes, why and what specifics? - If no , why and what specifics?
20) What strategies did you use to deliver the PRIDE intervention? - Use of DAW manual - Use of PRIDE manual - Training in delivery of intervention - Support from PRIDE team - Support from colleagues - Other things
21) Is there anything else that you would like to say about the issues we have talked about?

Table 3: Persons with dementia baseline (BL) and follow up (FU) scores

	Baseline (N=34)	Follow Up (N=27)	T-tests (N=27)
Questionnaire	**Mean (SD)**	**Mean (SD)**	**T-test (p)**
Engagement and Independence in Dementia Questionnaire (EID-Q)	81.40 (15.89)	83.74 (12.42)	-.55 (.59)
Control, autonomy, pleasure, and self-realization (CASP 19)	23.22 (6.07)	22.70 (5.56)	.63 (.53)
Impact on Participation and Autonomy (IPA)	6.95 (3.06)	6.67 (3.44)	-.15 (89)
Positive Psychology Outcome Measure (PPOM)	49.51 (9.30)	50.81 (50.81)	-.88 (.39)
Self Management Abilities Scale 30 (SMAS 30)	91.94 (17.17)	98.19 (13.55)	-1.46 (.16)
ICECAP-O*	15.24 (2.40)	15.96 (2.27)	-1.65 (.11)
EQ5-D (Health related quality of life)	.80 (.23)	.81 (.23)	-1.38 (.18)
EQ5-D VAS	70.97 (18.50)	74.56 (18.82)	-1.32 (.20)
Timed Get up and Go (TUG)	15.17 (6.04)	13.60 (8.29)	1.28 (.21)
Hopkins Verbal Fluency and Learning Test (HVLT) Total	11.09 (4.60)	12.34 (5.2)	-1.41 (.17)
Dementia Quality of Life (DEMQOL) Total	91.56 (13.21)	91.85 (16.37)	-.74 (.47)
Standardized Mini-Mental State Examination (SMMSE)	23.97 (4.24)	22.85 (5.61)	-2.03 (.05)
ELSA: ELSA self-perceived social connectedness	5.65 (1.43)	5.68 (1.21)	0.00 (1.0)
The Bristol Activities of Daily Living Scale (BADLS) *	13.03 (7.86)	11.75 (8.02)	1.49 (.15)
(Dementia Quality of Life (DEMQOL) Total *	95.53 (10.78)	96.23 (11.12)	-3.06 (.30)
EQ5-D Proxy*	.65 (.23)	.69 (.20)	-.53 (.60)
EQ5-D VAS Proxy *	63.38 (18.05)	64.92 (17.15)	-.04 (.96)

High scores indicate better well-being except on the IPA, EQ5-D and ELSA. * Note. N=26

Table 4: Supporters baseline (BL) and follow up (FU) scores

	Baseline (N=34)	Follow Up (N=26)	T-Test (N=26)
Questionnaire	**Mean (SD)**	**Mean (SD)**	**T-test (p)**
ICECAP-O	13.47 (3.06)	14.54 (3.29)	-1.68 (.11)
EQ5-D	.74 (.24)	.78 (.22)	-.42 (.68)
EQ5-D VAS	76.35 (13.58)	81.46 (11.64)	-2.04 (.04)

Note. High scores on ICECAP-O scores indicate greater wellbeing, high scores on EQ5D indicate lower wellbeing.

Table 5. Enactment of the PRIDE intervention and SMAS scores. Post hoc exploration.

	Mean SMAS	
	Baseline	Follow up
Self -reported Enactment Time 2*		
76-100% enactment	97.64 (SD 15.60; n=10)	97.70 (SD 10.43; n=10)
≤75% enactment	78.61 (SD 16.28; n =9)	96.42 (SD 12.87; n= 9)
Self -reported Enactment Time 3		
76-100%	97.58 (SD 18.73; n= 9)	94.90 (SD 16.03; n = 9)
≤75%	77.50 (SD 21.00; n= 5)	96.35 (SD 13.82; n=5)
Unknown	92.94 (SD 16.07; n=11)	104.50 (SD 9.95; n=4)

*Enactment was measured after interventions sessions 2 and 3 only.

Note. N's in the unknown group are those who did not complete either the T2 or T3 enactment question

(For more details on the overall engagement scores see Walton et al, 2018[23]).