

Title: An intervention to improve sleep for people living with dementia: Reflections on the development and co-production of DREAMS:START. (Dementia RElAted Manual for Sleep; STrAtegies for RelaTives)

AUTHORS

Penny Rapaport, MPhil^{1*}, Lucy Webster, Rossana Horsley⁵, MSc¹, Simon D Kyle, PhD⁴, Kirsi M Kinnunen PhD¹, Brendan Hallam, BSc¹, James Pickett, PhD⁶, Claudia Cooper, PhD^{1,2}, Colin A Espie, PhD⁴, , Professor Gill Livingston, MD^{1,2}

1 Division of Psychiatry, Faculty of Brain Sciences, UCL, Maple House, 149 Tottenham Court Road, W1T 7NF, London, UK

2 Services for Ageing and Mental Health, Camden and Islington NHS Foundation Trust, London, UK

3 Department of Statistical Science, Faculty of Mathematical & Physical Sciences, UCL, London, UK

4 Sleep and Circadian Neuroscience Institute (SCNi), Nuffield Department of Clinical Neurosciences, University of Oxford, Oxford, UK

5 Alzheimer's Society Research Network, 43-44 Crutched Friars, London, EC3N 2AE, UK

6 Alzheimer's Society, 43-44 Crutched Friars, London, EC3N 2AE, UK

*Corresponding author p.rapaport@ucl.ac.uk

ABSTRACT (248 WORDS)

Many people living with dementia experience sleep disturbances yet there are currently no known effective, safe and acceptable treatments. Working with those affected by dementia to co-produce interventions is increasingly promoted to ensure that approaches are fit for purpose and meet the specific needs of target groups. Our aim here is to outline and reflect upon the co-production of DREAMS:START (Dementia RElAted Manual for Sleep; STrAtegies for RelaTives); an intervention to improve sleep for people living with dementia.

Our co-production team brought together experts in the development and testing of manualised interventions in dementia care and cognitive behavioural interventions for sleep disorders, with Alzheimer's Society research network volunteers (ASRNVs) whose lives had been affected by dementia. Here we present the process of intervention development. We worked with ASRNVs at each stage of the process bringing together 'experts by training' and 'experts by experience'. ASRNVs shared their experiences of sleep disturbances in dementia and how they had managed these difficulties, as well as suggestions for how to overcome barriers to putting the intervention into practice; making DREAMS:START more accessible and usable for those in need.

In this paper we discuss both the benefits and challenges to this process and what we can learn for future work. Collaborating with 'experts by experience' caring for a relative with sleep difficulties helped us to develop a complex intervention in an accessible and engaging way which we have tested and found to be feasible and acceptable in a randomised controlled trial.

Lessons for practice: What worked and what would we recommend to others?

- Working with those with 'experts by experience' whose lives had been affected by dementia at all stages of the project enabled us to co-produce a complex and technical intervention in an accessible and usable form.
- Working with 'experts by experience' in a co-production process does not have to be a choice between disregarding our own professional academic and clinical expertise or 'tokenistic involvement' of PPI partners.
- Openly discussing any differences in perspectives and being transparent about how decisions have been reached and where intervention content comes from can help navigate this process.
- Being flexible with processes and having a range of ways for 'experts by experience' to share their views and experiences can make it easier for those affected by dementia to contribute and can result in a more diverse group of individuals being able to participate.
- Having ongoing conversations with those contributing to the PPI about their experiences of the process and how they feel it could be improved enabled us to refine the process as it evolved and learn from our mistakes.
- In addition to material and financial remuneration for their time, making sure that those who participate are given the opportunity to hear how their contribution has made a difference and sharing any outcomes of the research as they become available is a key part of the process.

AIM

Background to the research

Sleep affects all aspects of mental and physical functioning and quality of life (Kyle, Espie, & Morgan, 2010). Many people with dementia have sleep disturbances (Dauvilliers, 2007; Moran et al., 2005), with one meta-analysis reporting sleep problems in 39% of people with Alzheimer's disease (AD) (Dauvilliers, 2007; Moran et al., 2005; Zhao et al., 2016). Dementia can lead to impaired sleep initiation, reduced night-time sleep, difficulty maintaining sleep, increased night-time wandering, and excessive daytime sleepiness (Cagnin et al., 2017; Dauvilliers, 2007; Moran et al., 2005). Sleep disturbances in dementia mean that family members may be woken by the person with dementia, or feel they are unsafe at night (Gehrman, Gooneratne, Brewster, Richards, & Karlawish, 2017; McCurry, Logsdon, Teri, & Vitiello, 2007).

There is no conclusive evidence that any medication for sleep problems in dementia is effective, and they may cause harm (G. Livingston et al., 2017; McCleery, Cohen, & Sharpley, 2014). Patients and their doctors also prefer non-drug approaches (Dzierzewski, O'Brien, Kay, & McCrae, 2010), which should therefore be the first line for sleep management. However, most evidence to date comes from small-scale methodologically weak studies with high dropout rates, and current treatment strategies are extrapolated from other illnesses, or are based on insufficient, conflicting evidence (Kinnunen, Vikhanova, & Livingston, 2017).

Patient and public involvement (PPI) is increasingly recognized as integral to all stages of health and social care research processes (Department of Health, 2005; Staley, 2009; Staniszewska, 2009). High quality PPI improves the quality of research outputs and benefits the research teams who have increased understanding and improved relationships with the participants and benefits patients and public who feel valued and empowered (Brett, Staniszewska, Mockford, Herron-Marx, et al., 2014; Brett, Staniszewska, Mockford, Herron-Marx, et al., 2014).

Dementia charities along with national and international research networks' policy, promote meaningful involvement of those affected by dementia in research (Alzheimer's Europe, 2011; Alzheimer's Research UK, 2016; Alzheimer's Society, 2017; Department of Health, 2005), although there are few good practice examples documented (Gove et al., 2017; Iliffe, McGrath, & Mitchell, 2013; Kelly et al., 2015). The Alzheimer's Europe position paper on involving people with dementia in research highlights co-production as an important aspect of PPI and how including those living with and affected by dementia can enhance intervention quality and relevance (Gove et al., 2017). In the context of this paper, we refer to co-production as the process of collaborating with multiple stakeholders from professional, academic and especially lay communities (Bovaird, 2007; Gove et al., 2017) as a means to ensure the relevance and acceptability of interventions in diverse settings (Davies et al., 2016; Wherton, Sugarhood, Procter, Hinder, & Greenhalgh, 2015). Co-production in dementia care is a way to ensure that interventions and services meet the target population's needs (Boyle & Harris, 2009; Elliott, Stirling, Martin, Robinson, & Scott, 2017).

Aim for this study

It is important to consider how to make interventions practical, relevant and feasible at all stages of development and testing (Vernooij-Dassen & Moniz-Cook, 2014). Our vision In the DREAMS:START (Dementia RElAted Manual for Sleep; STRategies for RelaTives) feasibility and acceptability randomised controlled trial (RCT) was to build upon the existing incomplete evidence for non-

pharmacological approaches to sleep difficulties in dementia and our previously successful work with START (STrAtegies for RelaTives) (G. Livingston et al., 2013; G. Livingston et al., 2014), by co-producing and testing an intervention to be delivered to carers of people with dementia and sleep disturbance. We intended to integrate meaningful PPI at each stage of developing the DREAMS:START manual and in the research process, bringing together ‘experts by training’; academics and clinicians in the field and ‘experts by experience’; people whose lives have been affected by dementia, (Nolan, Ryan, Enderby, & Reid, 2002) to co-produce and test the new intervention. In this paper we outline and reflect upon the co-production process, informing broader learning in the dementia research community.

METHODS

Co-production team

Our co-production team brought together experts in the development and testing of manualised interventions in dementia care (GL, PR, CC), experts in manualised cognitive behavioural interventions for sleep disorders (CE, SK), and Alzheimer’s Society research network volunteers (ASRNVs) whose lives had been affected by dementia. JP coordinated input from the ASRNVs and RH led the PPI, contributing at all stages of the research. ASRNVs were initially approached by the Alzheimer’s Society. We extended the invitation to both people living with dementia and their carers. If they expressed an interest in becoming involved, we approached them directly via email. We reimbursed ASRNVs for their time in attending meetings in line with the INVOLVE guidelines (INVOLVE, 2013). In addition to payment, we gave focus group attendees a £20 high street shopping voucher, covered travel expenses and provided refreshments. Ethical approval for the study was obtained from the London – Queen Square Research Ethics Committee (Reference: 16/LO/0670).

Process of co-production

We developed the DREAMS START intervention using an iterative and collaborative process, summarised in Figure 1. There are different approaches to PPI in research described by INVOLVE as consultation, collaboration and user controlled (INVOLVE, 2012), although they highlight that in complex research these approaches are often combined and boundaries between them are not clear cut. In this project, we predominately used consultation (with ‘experts by experience on the intervention development) and collaboration (working with our PPI co-author in an ongoing partnership) in our co-production process.

Stage 1 & 2 Literature review and first draft

We began developing the intervention in February 2016. In April the co-production team (PR, GL, CC, SK, CE, KK, RH, JP) agreed DREAMS:START would be a six session multicomponent intervention, combining *content* incorporating the best existing evidence (Brown et al., 2013; Forbes, Blake, Thiessen, Peacock, & Hawranik, 2014; Montgomery & Dennis, 2003; Sivertsen & Nordhus, 2007), *structure and form* from our previously successful manualised interventions (G. Livingston et al., 2013; G. Livingston et al., 2014), and *context and process* informed by our input from ‘experts by experience’, incorporating some existing materials from START and SK and CE’s CBT earlier work (Espie, 2006; Espie et al., 2007).

We initially agreed the intervention’s main structure and content, and that it would be interactive and individualised. Actigraphy data (from a non-intrusive, re-usable wristwatch which monitors movement and estimates sleep/wake patterns), collected at baseline, would inform shared

understanding of the person with dementia's sleep. We adopted a non-prescriptive model explicitly encouraging family carers to build upon their experience of what works, and to develop and use new techniques and behavioural strategies. In line with the earlier START intervention, each session included a stress reduction exercise, a practice task between the sessions, a recap on the previous session, and troubleshooting around putting strategies into practice.

PR and SK developed the manual's six initial drafts, and circulated sessions within the team and revised based on feedback on form and content. We included theoretical components, clinical vignettes and practical exercises based upon the carers' own experiences, which were discussed during the sessions. We avoided large chunks of technical information and presented information in a clear and visually engaging manner. We sought direct feedback on this during stages 3-7 of the process.

Stage 3 learning from experts by experience

After initial revisions, we invited ASRNVs with relevant experience to attend a focus group (May 2016) to inform future drafts and to share their experiences of strategies they did and did not find useful. The group was facilitated by PR and KK, based upon a semi-structured topic guide (See Appendix A). Although we invited all ASRNVs, no people living with dementia chose to attend the focus groups. Four people (two current and two former carers of people with dementia) attended the focus group. They gave written, informed consent to audio recording the discussion. It was then professionally transcribed, and we entered the data into NVivo 11 software and analysed it using thematic analysis (Braun & Clarke, 2006). We further revised the manual based upon this initial feedback, then consulted a virtual reference group, including the focus group participants, and people living with dementia via email, to gain additional perspectives. The group included three additional ASRNVs (one person living with dementia and one current and one former carer).

Stage 4-7 on-going refinement and finalising the intervention

PR further revised the manual based upon experts by experience's feedback, then drafted a therapist version of the manual with prompts and guidance for the therapists. The team then checked the manuals for readability using the Flesch reading ease test (Flesch, 1948). The research assistants who were going to deliver the intervention then practiced each session in pairs, with GL, PR, CC and KK making further revisions to timing, content and structure whenever it did not flow well, was unclear, too long or repetitive. This was repeated until the researchers and therapists agreed the sessions were satisfactory and the final versions were agreed with the wider co-production team. The manual's final versions were then produced for the study.

Stage 8 Consulting with experts by experience after the trial

The manual was then tested in a RCT for feasibility and acceptability (Gill Livingston et al., Submitted). After the RCT's completion, five carers who had contributed to the intervention development process attended a follow-up focus group facilitated by PR and LW and hosted by JP. The same procedures were followed for data collection and analysis as in the earlier focus group. (See Appendix B for semi-structured topic guide).

STUDY RESULTS

Outcome of pre-intervention focus group with experts by experience

The key themes elicited from the focus group related to (i) the sleep disturbances people with dementia experienced, (ii) the explanations carers had for these difficulties, (iii) the effects of these difficulties, (iv) what carers found helpful, and (v) their suggestions for the DREAMS:START intervention.

Experiences and understandings of sleep difficulties

The main difficulty carers described was their relative waking repeatedly in the night and getting up. This increased perceived risk of their relative coming to harm, for example by falling down the stairs or by using electrical appliances unsafely. Carers attributed this night-time waking to various causes; mainly their relative mixing up night and day, feeling that their relative was worried or anxious, and dementia type and severity. One carer felt this inability to tell whether it was day or night was exacerbated by their relative being indoors and inactive during the day.

The impact of sleep difficulties

All carers in the focus group spoke of the emotional, physical and practical impact their relative's sleep disturbance had on them, their relatives and other family members. The main effect related to the carers becoming sleep deprived, both by being woken up directly and because worrying about their relative coming to harm kept them awake even when their relative slept. Carers described how the lack of sleep had negatively affected their physical health and ability to work and function effectively during the day.

What works?

Carers highlighted successful and unsuccessful strategies they had used, describing how gentle touch and physical comfort relaxed their relatives at bedtime and during the night, and that winding down before bed was helpful. They also highlighted the importance of carers finding ways to manage their own stress and sleep problems. There was consensus among the carers that using medication to manage sleep problems in their relatives was not helpful. They also explained that sometimes there did not seem to be any pattern to the sleep problems and nothing helped.

Suggestions for refining the draft intervention

Both the focus group participants and the virtual reference group participants gave feedback and made suggestions about different aspects of the sessions, summarised in Table 1, below.

Finalised intervention used in trial

The DREAMS:START manual was designed to optimise both the person with dementia's sleep at night and his/her wakefulness during the day. Sessions one to five all included one or two key topics for discussion, a specific plan or goal to try out between sessions, a stress reduction exercise with an accompanying CD/MP3 file, and a sleep diary for the carer to fill in for monitoring progress. Although manualised, during each session the participants would develop specific goals centred on the individual difficulties of the person for whom they cared, which were combined to make a written individualised plan.

Outcome of post-intervention focus group with experts by experience

The key themes elicited from the post-intervention focus group related to what the carers liked about the intervention, what they felt should be added or enhanced in future versions, perceived barriers to delivery and effectiveness of the intervention, and general suggestions for a future full clinical and cost-effectiveness trial of DREAMS:START.

Positive feedback on the finalised intervention

The focus group participants highlighted aspects of the intervention which they thought were useful and important. In terms of content, they felt a focus on behavioural activation and physical activity was important for carers and people with dementia and could lead to a reduction in daytime napping and night-time wakefulness. In terms of process, the carers highlighted how combining a methodical, manualised and structured approach with support from a therapist to put strategies into practice and troubleshoot difficulties was beneficial. They also appreciated the flexible and personalised delivery of the intervention, and felt it was easy to read and follow.

Perceived challenges

One of the main challenges perceived by the focus group participants was that increasing activity or making daytime changes, especially if the person with dementia lives alone, relies upon service provision which in their experiences was often unavailable. They questioned whether it was better to offer intervention only to those people with dementia who had someone living with them to support them to put changes into practice. They also perceived the intervention to be harder both to deliver and implement if the person with dementia did not recognise they had a sleep problem or understood it differently from their relative.

Suggestions for future adaptation and testing of DREAMS:START

Focus group participants thought it would be useful to build technology into future iterations of the intervention. Carers suggested app-based technology to remind carers to try a particular strategy at a set time and to facilitate real-time recording of bed and getting up times. On hearing about the qualitative findings from the intervention, the carers also suggested that future versions of the manual should be even more personalised, with more detailed instructions for therapists mandating them to leave out parts that were not relevant. They suggested including more detailed vignettes of the sleep difficulties people with dementia may experience, based upon the data collected in this feasibility study. Although they had not themselves directly experienced the intervention, focus group participants felt that having a peer support component, where participants could either directly or virtually connect with others participating in the intervention, might both validate the emotional responses of family carers and provide them the opportunity to learn from each other.

DISCUSSION AND CONCLUSIONS

In order to develop a practically useful intervention with potential to positively impact on the lives of those living with dementia and their families, we worked with ASRNVs at all stages of the research process. In addition to their contribution to the initial setup and development of the project and subsequent oversight of the research process, we worked with ASRNVs to co-produce the DREAMS:START intervention including them in both consultative and collaborative roles at different stages (INVOLVE, 2012).

We used the findings from our focus groups to inform the manual, ensuring that the emergent themes highlighted above were included and, in particular, that there was a greater focus upon carers finding ways to minimise the impact of sleep disturbances on their own wellbeing and ensure that the person with dementia was physically and emotionally comfortable. We added direct quotations from the carers about their experiences to situate the content and highlight the experiences of family carers. We amended content to include family carer experiences of feeling that sometimes nothing seems to help, and to emphasise that people with dementia are not to blame for, or responsible for, any difficult sleep-related behaviours.

In our post-intervention focus group when we presented the qualitative and quantitative findings of the study, including detailed experiences of those who had received the intervention, all of the ASRNV participants questioned or expressed frustration that the manual would not be widely available until a full RCT had been completed. In addition to their suggestions about future refinement of the intervention we had a useful discussion about what they felt was the most important 'outcome' for a future trial. The focus group participants felt that there needed to be a continued focus on improving carers' sleep as well as on the sleep of people with dementia and the impact that this has on quality of life and mood rather than a more narrow focus on measuring time spent asleep and awake.

In focusing on the important clinical issue of sleep disturbance in dementia we were bringing together wide ranging technical information from across different academic disciplines. In an effort to find solutions to a complex clinical problem we had a tendency to become overly technical and mechanistic. Our ASRNV collaborators ensured our work was consistent with our overall aim to develop a useful and practical intervention. Working with people caring for a relative with sleep difficulties helped us to stay focused on the person with dementia and their family and develop an intervention with complex content in an accessible and engaging way.

REFLECTION AND CRITICAL PERSPECTIVE

In developing the DREAMS: START intervention we were not starting with a blank slate; we were basing the content and structure of the proposed intervention upon the existing evidence base and our own academic and clinical expertise in the field. We attempted at all stages in the research process to balance this professional expertise with lay expertise. We acknowledge, however that, since this process was ultimately led by the academic research team, we may not have always given equal weight to the views and ideas from our 'experts by experience', and the process therefore remained professionally dominated (Ocloo & Matthews, 2016). One way that we tried to redress this power imbalance was to build the words of the participants in the focus group into the intervention, thus explicitly presenting this personal experience alongside expert knowledge, as fully integrating it would have rendered it invisible. However, we also judge it would be irresponsible to ignore the available evidence which is qualitatively and quantitatively different to an individual experience. This was not always an easy process to navigate, particularly when the experts by experienced made suggestions which directly contradicted academic and clinical expertise. At these times we made efforts to respectfully discuss these differences openly with those contributing and to be transparent about our decision to include or exclude a particular suggestion.

During the process of intervention development, all of our PPI came via the Alzheimer's Society research network and ultimately we were working with a relatively small group of committed individuals whose lives had been affected by dementia. Patient representatives in research are less commonly from black and minority ethnic backgrounds and are less likely to come from socio-economically disadvantaged groups, limiting the opportunity to develop a greater understanding of ways to widen access and develop interventions that are fitting and meet the needs of marginalised groups (Ocloo & Matthews, 2016). During the feasibility RCT and the qualitative interviews we conducted as part of the evaluation however, 35% participants came from black and minority ethnic backgrounds and we have used their experience of the intervention to further improve it. Another issue which occurred during the course of the co-production process was that family carers contributing to the PPI often had difficulties attending our meetings because of their relatives' or their own health problems and other practical considerations. It was for this reason that we thought the virtual reference group would be a good way for people unable to attend a face to face meeting to contribute to the process and in we will continue in future projects to find flexible and creative ways to ensure that those who cannot attend meetings can contribute.

From the out-set, we were interested in involving people living with dementia and their carers in the co-production process and our initial invitation was sent to all ASRNVs. Although one of the members of the virtual reference group was a person living with dementia, the rest of those who contributed to the PPI were family carers of those with dementia. We learned from this the importance of more actively finding ways to include people living with dementia and perhaps engaging with a wider range of services to widen access to the process. Since we were developing an intervention to be delivered primarily to family carers, we were interested in their perspectives of caring for a relative with dementia and sleep difficulties. However, this did mean that the voices of people living with dementia themselves were less prominent in the process although family members talked about them. Thus in all the conversations with family carers during the intervention development, we considered the perspective of those that they had been caring for, what was important to them, and how the intervention would fit their lives. Based upon our own reflections and our conversations with family carers, we also thought carefully about the way we talked about sleep disturbances in the intervention – making sure to separate the 'person' from the 'problem' being discussed (Milton & Hansen, 2010).

Word count (3565)

Acknowledgements

We would like to thank the participants and referrers and all the ASRNVs that contributed to this project. We would also like to thank the members of the Trial Steering Committee – Esme Moniz-Cook (Chair), Kate Maxmin, Judy Leibowitz, Sue Boex and John Cape and Rebecca Turner and Adam Kadri for delivering the intervention. The DREAMS-START research team acknowledges the support of the National Institute for Health Research through the North Thames Clinical Research Network.

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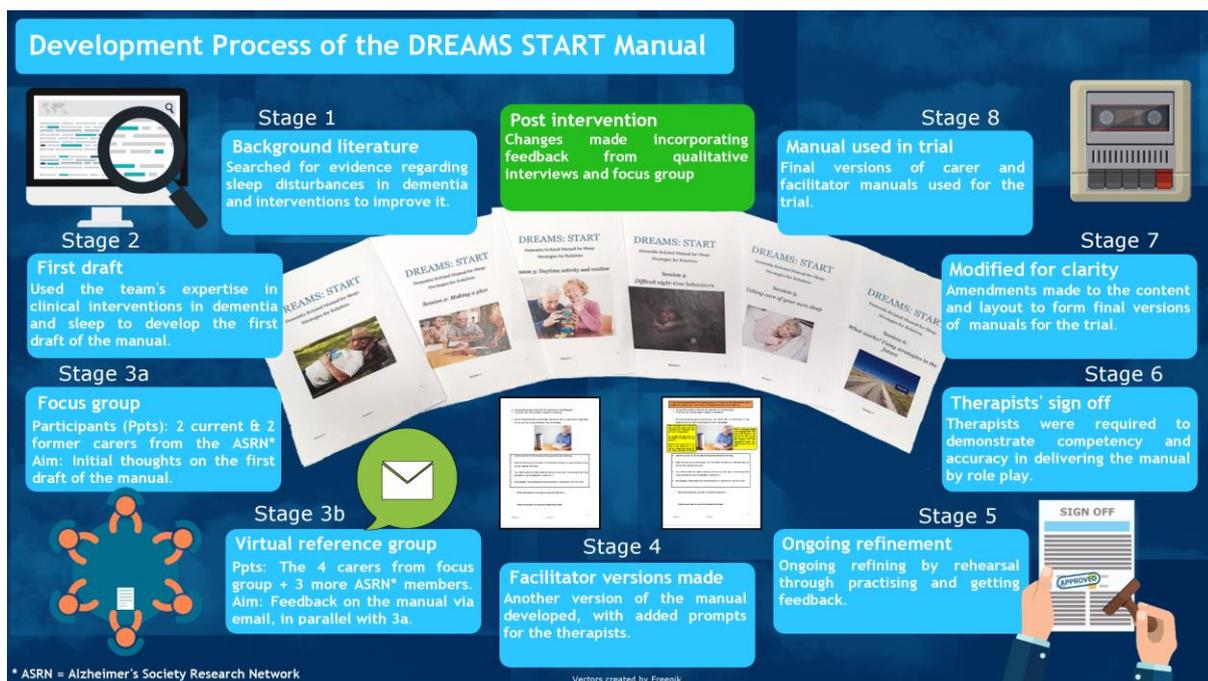


Figure 1: Process of intervention development

Table 1: Suggested changes to the draft intervention by focus group and virtual reference group

Content	<ul style="list-style-type: none"> To include more on the impact of different dementia types on sleep To make session one less didactic To explain the actigraphy data very simply To include discussion of becoming more agitated or confused in the evening To include more on physical causes of sleep problems including medication To focus on increasing activities at times person is most likely to nap To mention the impact of nutrition on sleep
Design	<ul style="list-style-type: none"> To reduce the number of words/page and overall To include more pictures in order to make the manual more readable To ensure any instruction to carers is very detailed and clear To simplify the diagrams delineating sleep processes To change specific pictures which were not felt to fit Formatting and typographical errors were identified
Session delivery	<ul style="list-style-type: none"> To emphasise potential benefits of the intervention and how the intervention could help and make life easier To ensure that the tone of this was as a partnership, working together with the carer rather than teaching them To respect the carer's existing knowledge and experience To allocate more time for session one or reduce the content