

Involving service users in the development of the Support at Home: Interventions to Enhance Life in Dementia Carer Supporter Programme for family carers of people with dementia

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Abstract

Background Involving service users in research can be an effective way of improving the practicalities and acceptability of interventions for target end users.

Objectives The current paper presented two consensus methods, not commonly used in consultation with service users, to develop a peer support intervention for family carers of people with dementia (SHIELD Carer Supporter Programme).

Design Study 1 was a modified Delphi process combined with a consensus conference to explore details of the intervention from the carer and volunteer perspective. Study 2 was an anonymous reader consultation to develop informed consent documents for the intervention trial. Median scores were used to measure and establish consensus. Open-ended responses were thematically analysed.

Setting and participants Study 1: twenty-five delegates participated (eight were current/former carers) in the first round Delphi questionnaire, with 21 attending the conference. Five completed the Round 2 questionnaire. Study 2: six family carers and 11 people with dementia took part in the consultation.

Results Study 1: the role of the peer supporters was developed in terms of relational and practical aspects of the intervention. Study 2: changes were made to the documents, reflecting service user input, but the effectiveness of this less discursive type of service user involvement was unclear.

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Discussion and conclusions Study 1 methods allowed for service users to contribute significantly and meaningfully, but maybe limiting some design innovation. Study 2 took a more traditional and less collaborative approach. This has implications for balancing the needs of the research with meaningful service user involvement in research.

Background

Peer support interventions are increasingly used, especially in the UK, to encourage people to self-manage chronic illness.¹ This has led to policy strategy for the development of interventions to support carers of people with chronic illness, specifically family carers of people with dementia.² The involvement of service users and carers in developing and researching such interventions is increasingly recognized as important to ensure their relevance and acceptability, but may raise particular challenges for those living with or caring in dementia.

Service user involvement enhances the appropriateness of interventions and aids retention of trial participants,³ but there is a lack of empirical outcome-based evidence concerning the methods that most effectively involve service users.⁴ Researchers can be reluctant to involve service users as a potential source of subjective bias undermining research quality⁵ but such involvement can help develop more theoretically coherent and evidence-based interventions, more likely to be practical, generalizable and meaningful for potential users.

The intervention in the current study was developed from the Befriending and Costs of Caring (BECCA) trial of a carer support intervention in which trained volunteer lay workers befriended family carers of people with dementia for companionship and conversation.⁶ In this trial, access to a befriender was not effective in improving well-being. This might have been due to poor uptake of the befriending intervention. In addition, befrienders did not necessarily have personal experience of caring for a relative with dementia, but the most successful volunteers were ex-carers, or peers.

This study describes the involvement of service users in developing the peer support intervention for the Support at Home: Interventions to Enhance Life in Dementia (SHIELD) programme⁷ through consensus methods not commonly participated in by service users.⁵ These included a consensus process to develop the intervention (Study 1) and a consultation to develop information and

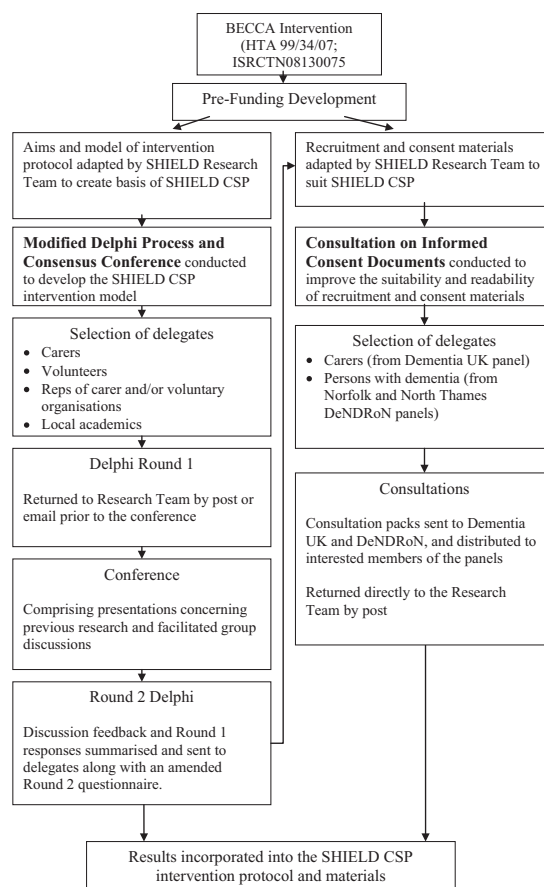


Figure 1 Model of consensus methods used in the development of Support at Home: Interventions to Enhance Life in Dementia Carer Supporter Programme.

consent documents (Study 2) (see Fig. 1). Both retained principles of good involvement practice (i.e. clarity and transparency, respect, diversity, flexibility and accessibility) and meaningful involvement.⁸

Study 1 modified Delphi and consensus conference

Aim

To develop the peer support intervention from the carer perspective in consultation with service users.

Design

A combination of a modified Delphi Process^{9,10} and a consensus conference¹¹ were used to examine the peer support programme from carer and volunteer perspectives. This combination aimed to allow participants to respond personally and privately, while also offering an opportunity to discuss ideas and concerns.

Participants

Service users and stakeholders were approached through relevant organizations: family carers, peer support and voluntary work, NHS organizations and Universities. Twenty-five people completed Round 1 of the modified Delphi process. Of these, 21 attended the consensus conference. The delegates comprised eight current and former carers, seven members of voluntary organizations supporting carers and people with dementia or representing volunteers, three clinical health professionals, an academic specializing in the area, and two others (did not specify). Round 2 was sent to the original 25 stakeholders as well as to an additional eight that had become involved as the project progressed. In Round 2, five questionnaires were returned from three former family carers (one of whom had also worked with carers), one current family carer and one representative of a charity for people with dementia and their carers.

Method

Three weeks before the consensus conference, a Round 1 Delphi questionnaire was sent together with copies of the draft participant information sheets and recruitment materials to provide context for the proposed peer support intervention. Delegates were asked to complete the questionnaire before the conference either posting it back or handing it to the research team at the conference. The questions concerned the intervention name, role of the peer supporter, content and duration of training, desirable peer supporter characteristics, criteria to be used to match peer supporters and family carers (matching criteria), support for peer supporters and monitoring the matches for research purposes. These items were developed by the research team with reference to the service user feedback for BECCA and ideas and concepts trialled by other research groups in their work with peer supporters.^{12–14}

During the conference, Round 1 data were analysed and the results presented for discussion. Delegates were split into smaller groups organized to create heterogeneous groups as these can be the most productive when aiming to explore uncertainties and develop ideas.¹⁰ Each group was given a question from Round 1 to focus on facilitated by a research team member who made notes on flip-charts to feedback to the larger group and to be used as a record of discussions.

After the conference, Round 1 results were re-analysed to identify areas where consensus had not been reached. Each question was scored on a six-point Likert-type scale measuring strength of consensus (where 1 = perceived to be unimportant/unsuitable/unfeasible and 6 = perceived to be important/suitable/feasible). Delegates were also asked to rate their most preferred and least preferred options. Responses to the question items were summarized as medians, as being more robust than means and better indicating distribution of consensus as opposed to central tendency.¹⁰ Higher medians indicated higher importance/suitability, and percentages also being calculated

for most preferred and least preferred options. These two response formats gave both the extent of overall consensus (through most/least preferred options) and the strength of consensus (medians). Scores from all delegates were given equal weighting, regardless of perceived 'expertise', so as not to give service users a smaller contribution than those working professionally in the area.

Items with the lowest medians (1 and 2) were excluded from Round 2 as being unsuitable/irrelevant. Items with highest medians (5 and 6) were excluded from Round 2 as they were deemed suitable and agreed upon. Items with median scores between 3 and 4 were included in the Round 2 questionnaire along with information, to clarify areas of confusion and disagreement. Definitions and further information were provided in Round 2 to set out some distinction. In Round 2 questionnaires, more space for open-ended responses was given to allow delegates to clearly outline their views reducing the need for a third round. Thematic analysis was carried out for all open-ended responses. Analysis was inductive (data driven) with themes defined as specific patterns of interest within the participants' responses.¹⁵ A third round was found to be unnecessary as disparate views had been resolved at the end of the Round 2. The results from Rounds 1 and 2 (including the thematic analysis of Round 2

comments) are presented together to illustrate the delegates' contribution to the programme through the consensus process.

Results

Name of intervention and intervention providers

The peer support programme was planned at a time when the Expert Patient Programme was being evaluated, and the parallel initiative for 'Expert Carers' (known as 'Caring with Confidence') was in development. The term 'Expert Carer' has been used in different ways,¹⁶ but preliminary conversations with stakeholders made it clear that even the most experienced family carers were uncomfortable with the 'Expert' label. The programme was given the working title Experienced Carer Programme, in which peers would be referred to as 'experienced carers'. Because carers provide support to other carers, it was essential that service users had a part in naming the intervention. Delegates were presented with alternative names to describe the peer supporters and asked for further suggestions. The options included *Expert Carer*, *Mentor*, *Buddy*, *Experienced Carer* and *Carer Supporter*. Round 1 indicated that delegates felt peers providing the intervention preferred the terms *Experienced Carer* and *Carer Supporter* (see Table 1) with *Experienced Carer* most preferred, while *Buddy* was least preferred.

Table 1 Median scores for name of intervention (Delphi Round 1; *N* = 19)

Role of peer supporter	Median	Inter-quartile range	Most preferred %	Least preferred %
From peer supporter perspective				
Experienced carer	5	1	58.3	
Expert carer	4	2	8.3	7.7
Carer supporter	5	3	33.3	
Mentor	3	3		30.8
Buddy	3	2		61.5
From carer perspective				
Experienced carer	5	1.25	60	
Expert carer	4	2.25		8.3
Carer supporter	5	1.25	40	
Mentor	3.5	4		25
Buddy	1.5	3		66.7

6-point Likert-type scale (1 = Dislike Strongly; 6 = Strongly Like).

Conference delegates also saw *Experienced Carer* and *Carer Supporter* as preferred terms for people receiving the intervention with *Experienced Carer* ranked as most preferred, then *Carer Supporter*. To reach an effective consensus, a Nominal Group Technique was used.¹⁷ Delegates were asked to vote on potential names including those presented in the Round 1 questionnaire and a series of names suggested by the delegates during the nominal group. Two rounds of voting took place. In Round 2, *Carer Supporter* was most popular with 15 votes, while *Experienced Carer* received eight votes. *Carer Supporter* was preferred as it more accurately described the role of the volunteer and former carers objected to the term *Experienced Carer*, seeing the term 'experienced' as difficult to define. The intervention was therefore renamed the *SHIELD Carer Supporter Programme* (SHIELD CSP).

The role of the Carer Supporter

Delegates were also consulted on the types of support the Carer Supporters should provide to help build newer carers' confidence in their caring role. Median scores were five or more for all items other than specific training (see Table 1). In Round 1, *Providing Encouragement and Moral Support* was rated as most important. Delegates were less certain about the importance of Carer Supporters providing specific training or completing exercises from a 'toolkit' with the new carer. This was echoed in conference discussions focusing on the importance of building an open, flexible relationship based on trust, companionship and encouragement. Therefore, in Round 2, respondents were asked more specifically about the use of a 'toolkit' consisting of optional exercises that Carer Supporters could employ during their meetings with carers to aid communication¹³ such as asking newer carers to talk about: their role as carer and the obligations they may feel; the history of their relationship with the person they care for; their social circle to identify 'helpful others'; and any future concerns. Results indicated that a toolkit was not popular (Median = 2). Thematic analysis of open-ended responses from

former family carers depicted the role of the Carer Supporters as being to meet the needs of the carer, perhaps as simply as being there to listen, which was actually seen as being the most important aspect of the role:

'Not having someone to talk to is one of worst aspects of caring for someone with dementia. To have opportunity to talk with someone else who is caring, or has cared, is very valuable' (ID2)

Training content, duration and techniques

The Carer Supporter training aimed to provide good practice guidelines and support skills. The research team suggested specific training topics to achieve this such as information about dementia, services and resources, supporting self-care, problem-solving and the use of 'standard scripts' to introduce specified topics or tasks. In Round 1, all items but one were seen as important aspects of training (see Table 2). Responses from both the Round 1 questionnaire and consensus conference discussions indicated that, while it was important to be an emotionally supportive peer, Carer Supporters should also have a strong knowledge base about dementia and dementia services/resources. Delegates also gave weight to Carer Supporters being aware of the boundaries of their role, and to be trained to be able to say no to inappropriate requests. The use of 'standard scripts' to introduce specified topics or to help Carer Supporters break the ice at initial meetings received mixed reviews. Comments on questionnaires, alongside discussion during the conference, revealed delegates' uncertainty about what standard scripts might entail. Therefore, Round 2 provided more explanation for the term 'standard scripts' and sought opinions on their potential usefulness. Opinion remained divided with a range of scores between 1 and 4. Some saw standard scripts as very valuable, particularly a former carer who had also worked with family carers who explained:

'A standard script is extremely useful as a prompt to gaining all the required information. It is very easy to miss something important when

Table 2 Median scores for role and characteristics of Carer Supporter (Delphi Round 1; *N* = 19)

Carer supporter	Median	Inter-quartile range	Most preferred%	Least preferred %
Role of carer supporter				
Providing encouragement and moral support	6	0	50	
Listening to carers' experiences	6	0	37.5	
Signposting to services and/or resources	6	1		
Encouraging carer self-care	6	1		
Talking about common challenges of caring for a person with dementia	5	2	12.5	
Supporting problem-solving	5	2		
Chatting about life outside/beyond caring	5	2		42.9
Meeting with both the carer and person with dementia	5	2		
Specific training tasks/exercises to compete with newer carer	4	1		57.1
Characteristics of carer supporter				
Ability to listen	6	0	62.5	
Tolerant attitude	6	0	25	
Keen to give advice	4	2		
Keen to share their experience	4	2		40
Keen to use their experience	5	2		40
Knowledgeable about dementia	6	0	12.5	20

6-point Likert-type scale (1 = Unimportant; 6 = Essential).

listening to a carer's issues that may prove useful in working with that person' (ID4)

Others had concerns, such as one former carer who wrote:

'If needing to resort to using standard scripts it could send out message about the lack of volunteers' skills, confidence and above all sincerity. It is the sincerity and empathy that are so important' (ID2)

Given the lack of consensus, it was decided to raise the use of standard scripts as a topic for discussion during pilot training sessions.

For the training programme duration, 19 (of 20) valid responses were received of which 14 (73.7%) confirmed that six 2-hour modules were adequate, delegates again highlighting the need for on-going support and training. Diverse techniques were planned for the training sessions, including short lectures, discussions, illustrative examples and role play, all having worked effectively in the BECCA training module. For the SHIELD CSP, other training techniques suggested for inclusion were *telling one's own story of caring*, *additional reading* and

video/DVD examples. Only these three techniques were included in Round 1 because they had not been used in BECCA. *Telling one's own story* and *video/DVD examples* were both seen as very suitable (see Table 3). *Additional reading* was positively received but after discussions during the conference was seen as least suitable as delegates raised queries regarding feasibility. This item was retained for Round 2 but opinions continued to differ with scores ranging from 2 to 6, indicating that participants felt it had limited feasibility. As a former carer wrote in Round 2:

'Some [Carer Supporters] may be interested in becoming more knowledgeable by additional reading, some may lose confidence if they feel they require and are required to have additional knowledge before being considered as a supporter..... For example, I am a book and research-oriented person; I know other former carers who are excellent carers but not interested in serious study' (ID1)

Another Round 2 question asking, if additional reading was not feasible, whether it would be appropriate for material to be

requested, was unanimously agreed as an option. A current carer summarized:

‘...not all Carer Supporters would like to do all recommended tasks. The information should be available with details of resources and no compulsion’ (ID3).

Carer Supporter characteristics

To identify the type of Carer Supporter who could be most helpful to the newer carer, a list of characteristics was presented for evaluation (see Table 3). All delegates agreed that the ability to listen was absolutely essential, prompting the strongest response to all questionnaire items with all 19 responses scoring this 6. A tolerant attitude and being knowledgeable about dementia were also found essential. Advice-giving continued to be less favoured, so was the sharing of experiences during meetings (despite one of the perceived values of an experienced carer being that they have common or shared experiences). Delegates felt that some carers may feel the Carer Supporter was ‘taking over’ with the envisaged worst consequence being that Carer Supporters may ‘off-load’ adding to the family carers’ burdens. Conference discussions revealed that delegates were unclear about the difference between using experience to guide discussion and sharing personal experiences, so in Round 2, the concepts of using and sharing experience were defined more clearly. *Using personal*

experiences was described as Carer Supporters using their experiences to assist carers in problem-solving or signposting to useful resources but not to give advice on courses of action. *Sharing personal experiences* was described as Carer Supporters talking about their own personal caregiving journey. It was also made clear that training would explicitly cover the importance of not ‘off-loading’. However, consensus was not reached as both approaches received a range of scores (Median = 4), perhaps indicating that the difference remained unclear. Thematic analysis revealed that, despite the varying scores, all delegates felt that sharing experiences was vital as the basis of the SHIELD CSP regardless of whether the question concerned sharing or using experience. As one former carer wrote:

‘Sharing experiences, exchanging information evoke a spirit of kinship among fellow carers and begins the learning curve of dementia care and coping strategies and other life experiences of living with dementia’ (ID3)

Nonetheless, all had concerns about the risks associated with allowing Carer Supporters to share their experiences. In particular, a representative of a dementia charity wrote:

‘After 17 years working with carers of people with dementia it is my experience that very few are able to be objective about their own experi-

Table 3 Median scores for training: content, duration and techniques (Delphi Round 1 $N = 19$)

Training	Median	Inter-quartile range	Most preferred %	Least preferred %
Topics for volunteer training ($N = 20$)*				
Information about dementia	6	0	55.6	
Information about services and resources	6	0	44.4	
Supporting self-care	6	1		
Supporting problem-solving	5	1		
Standard scripts to introduce specified topics or tasks/exercises ($N = 19$)	4	3		100
Training techniques ($N = 19$)†				
Telling one’s own story of caring	6	2	62.5	28.6
Additional reading	5	2	12.5	71.4
Video/DVD examples of recommended discussion topics/exercises	6	1	25	

*6-point Likert-type scale (1 = Unimportant; 6 = Essential).

†6-point Likert-type scale (1 = Unsuitable; 6 = Suitable).

ence. If some time has passed they may offer out of date information, or allow a bad personal experience to colour the conversation' (ID5)

Comments from delegates stated that they thought that giving advice should be avoided, while emphasizing that using and sharing experiences could be useful for signposting to useful resources, or simply portraying empathy, all highlighted the need for careful consideration before implementation. This discussion was taken forward to the pilot training.

Matching criteria

For the SHIELD CSP intervention to reach its full potential, newer carers needed to feel a warm and genuine connection with the Carer Supporters. Previous research suggests that peers and those they support be matched on a set of criteria associated with personal constructs and characteristics.¹³ However, experience from the BECCA programme highlighted the need for flexibility when making matches to take into account personal preferences and whether the relationships had warmth and empathy. To ensure balance between theory and practice, and to generate ideas concerning the most important characteristics for people to have in common, potential matching criteria were explored in Round 1 (see Table 2).

Psychological health (i.e. feelings of burden or mood state) was considered essential, along with view of caregiving (i.e. as burden, challenge to face, problems to solve). Being matched on marital status or employment status was considered unimportant, although during the conference discussions, marital status was seen as an important criterion. No firm consensus was reached on other matching criteria such as gender, age, relationship to care recipient and geographical location. A reason for this, suggested during the conference, was that certain criteria, perhaps gender, may be important to some but not to all. Further discussion during the conference led to the proposal of hobbies, religious or ethnic origin, and type of dementia and age of onset as matching criteria.

In Round 2, these criteria were explored further, and consensus was reached that, where possible, carers and supporters should have the option to be matched on gender, religious/spiritual views, cultural or ethnic background, and to a greater extent relative's age of onset. How sensitively such differences in experience could be viewed was highlighted by a former carer:

'If you have cared for someone with young onset, as I did, you are apt to get a bit irritated with someone who cared for someone in their 80s. It's not the same, as we share that sense of loss yes, but not that of an 'out of turn' experience which is so distressing where young family and all the other related issues come into play' (ID2)

Delegates felt that matching on interests and hobbies and type of dementia were not important. Indeed, some felt that different interests could stimulate conversation and interest, and with good training, type of dementia would not be important. As one former carer wrote:

'Supporter is providing companionship and moral support to someone who is tired, worn out and isolated. The support is for the carer, not the patient' (ID1)

It was decided that intervention organizers should ask participants and Carer Supporters about the characteristics on which they would like to be matched.

On-going support for Carer Supporters

Carer Supporters needed to feel supported in their role, and delegates were consulted on the best methods to achieve this. The research team suggested group meetings, individual face-to face-contact and additional training, all approved by the delegates. Additional comments from both Round 1 and conference discussions confirmed that local coordinators should provide on-going support, with more frequent contact encouraged during the first 3 months of the 10-month intervention. On frequency of contact, once a month was felt to be most appropriate ($N = 10$ of 19, 52.6%), although discussions suggested an 'open

door' policy of support, which has since been adopted.

Monitoring matches for research purposes

The frequency and nature of contact between Carer Supporters and carers needed to be monitored to assess how much intervention time the carers received. In Round 1, delegates were consulted on the best ways of monitoring contacts while avoiding burdening the Carer Supporters. Methods such as checklists, phone contacts and diaries were suggested. Of these, regular phone calls from the local coordinator to the Carer Supporter were judged as most feasible (Median = 6), while checklists were second (Median = 5). Comments during the conference warned against time-consuming procedures, which may explain the lack of support for completing a diary (Median = 4). The decision was made for Carer Supporters to complete a checklist of items administered by a coordinator during regular phone meetings.

Study 2 – informed consent document consultation

Aim

Informed Consent documents inform participants and help them decide whether or not to take part in the trial. The consultation aimed to ensure the appropriateness, suitability and readability of the consent documents (recruitment leaflet and information booklets for carers and their relatives with dementia).

Design

While local ethical review is commonly used to refine informed consent documents and related recruitment materials, this can lead to the documents becoming longer and less readable,¹⁸ making it more difficult to process important information.¹⁹ Readability should be 6–8th US grade reading level (about 11–14 years of age).²⁰ Researchers are increasingly also involving service users to develop informed consent docu-

ments often uncovering issues not appreciated by writers.²¹ Focus groups with readers who reflect the trial's target population are another popular way to create or develop informed consent documents.²² Developing public health information brochures often deploys the plus-minus method,²³ where readers place a 'plus' sign next to sections of the text they like and a 'minus' sign next to sections they dislike or feel could be improved. One-to-one interviews with a researcher then clarify and explore their preferences. This is a lengthy process requiring commitment from the readers. To manage time constraints and reduce the potential burden on readers, postal consultations were used in developing SHIELD CSP documents from materials for consultation adapted from the BECCA study. This is a novel approach, which offers logistical and practical advantages over existing methods.

Participants

As both carers and their relatives with dementia were to be participants in the SHIELD CSP, both groups were consulted. The consultation was anonymous, and the packs were sent to readers by post. Family carers were contacted through the Uniting Carers network of the charity *Dementia UK*. Persons with dementia were contacted through the East Anglia and North Thames hubs of the Dementias and Neurodegenerative Diseases Network (DeNDRoN) and were members of the Patient and Public Involvement Forum. In both cases, the research team sent consultation packs to identified gatekeepers at each organization who then forwarded the packs to interested parties. Demographic details were not requested from readers so as to distance the consultation from more traditional research paradigms.

Method

Before consultations, the research team incorporated the outcomes of Study 1 into the draft materials. While the main focus of the reader consultations was the recruitment leaflet

and information booklets, they were also sent draft consent forms to convey what participants were being asked to consent to and whether the information in the booklets conveyed this. Carers were asked to read the recruitment leaflet, information booklet for family carers and consent form. People with dementia were asked to read the information booklet for people with memory problems and corresponding consent form. Respondents were then asked to complete feedback forms concerning the clarity of information about the research study, what commitment would be required in taking part, information about right to withdraw from the research and booklet layout. Respondents rated clarity on a 5-point Likert-type scale (1 = no/not clear, 3 = partially clear, and 5 = yes/very clear) and the overall quality of each document (where 1 = low, 3 = moderate, 5 = high). Space was provided for respondents to write other suggestions and comments. In total, 12 carers and 12 persons with dementia consultations packs were distributed with six and 11 packs, respectively, returned.

Results

Median scores and inter-quartile ranges were calculated. Responses with median scores of 1–4 were taken as being unclear and actions were taken to amend these areas of concern. Reading Ease and grade level of the leaflet and information booklets were also assessed using the Flesch–Kincaid tests available in Microsoft Word.²⁴ The Flesch–Kincaid Reading Ease test is based on the average number of words per sentence and the number of syllables, taking into account the number of words about people in the passage and the number of sentences addressed to an audience. A score of 90–100 is considered easily understood by 11-year-olds, 60–70 is easily understood by 13- to 15-year-olds and 30 or below understood by graduates.²⁵ The Flesch–Kincaid Grade Level score rates text in terms of US school years: a score of 8.0 means that an eighth grade student (about 13 years old) would be able to understand the information and is the

recommended level of readability for standard documents for the general population.²⁵

Recruitment leaflet

Readers felt the recruitment leaflet was very clear, its layout easy to read and making the study purpose understandable and its details clear. Readers were less certain about the type of participants the study aimed to recruit. The leaflet was rated as being of high quality overall, but with some shortcomings. Readers' written comments helped to develop leaflet accessibility. For example, feedback indicated there was too much blank space and headings could be enlarged to improve readability, and the starkness of black and white printing might be softened by using glossy paper. To address these concerns, the text font and headings were enlarged to reduce the blank space and glossy paper was used. Through this process, the readability of the leaflet increased slightly, while reading grade level dropped slightly.

Family carer information booklet

Several elements of the booklet were rated highly, and overall, it was seen as being clear and detailed (see Table 4), importantly, in conveying information concerning withdrawal and implications for participating in the intervention. However, comments focused on layout and design rather than content, with some readers describing the booklets as having a 'daunting format' and 'rather clinical'. The panel suggested more breaks between sections to improve accessibility. The research team also added pictures to make the booklet less formal and more inviting. By making the suggested changes, the Reading Ease score increased and grade level decreased.

Information booklet for people with memory problems

The booklet was rated 'clear' but only the information regarding withdrawal from the study was rated as being 'very clear' (See Table 5).

Table 4 Median scores for matching criteria (Delphi Round 1 *N* = 19; Round 2 *N* = 5)

Matching Criteria	Round 1		Round 2	
	Median	Inter-quartile range	Median	Inter-quartile range
Gender	4	2	5	2
Marital status	2	2		
Employment status (including retirement)*	1	3		
Age	4	1	4	1.5
Education	3	3		
View of caregiving (e.g. as burden, challenge to face, problems to solve)	5	3		
Psychological health (e.g. sense of burden, mood state) [†]	5	3		
Relationship to care recipient	4	2		
Geographical location	4	2	3	4.5
Religious/spiritual views			5	3
Cultural/Ethnic background			6	1
Interests/Hobbies			2	3.5
Relationship to care recipient			3	4
Type of dementia			2	4
Age of onset			6	3

6-point Likert-type scale (1 = Unimportant; 6 = Essential).

Round 1

*Least important option (*N* = 2 of 7 responses, 28.6%).

[†]Most important option (*N* = 2 of 6 responses, 33.3%).

Comments to improve the layout included presenting the booklet as an invitation to participate rather than an extension of the family carer booklet and to use the word *informal* wherever possible to reduce the anxiety associated with official documents. It was also highlighted that in a booklet for people with dementia, the purpose of the study should appear at the beginning of the booklet to help people retain the information. Comments indicated that the purpose and role of Carer Supporters were not clear enough, and further clarification was needed about whether the carer could still have access to the planned interventions if the person with dementia did not want to participate.

As a result, the information booklet was made less formal and was styled more as an invitation. The interviews were described as informal, and the purpose of the study was presented first. A larger font was used, and the role of a Carer Supporter clarified along with reassurance that the carer could still be involved in the study even if the person with

dementia declined involvement. By making the changes, the Reading Ease score increased, while grade level decreased, see Table 6.

Using the documents in practice

These documents were later used in the pilot trial of SHIELD CSP resulting in a further round of amendments in response to comments raised by trial participants. Table 6 shows improvements made as a result of the reader consultations, but also show that there was very little additional improvement made as a result of participant feedback from the pilot.

It was noted that readers reviewed the documents at an abstract level for meaning, flow and format. Participants in the pilot trial may have reviewed the documents at a practical level to clarify the information and weigh up the personal implications of participating. Both types of consultation are important in developing consent documents, although the latter had little impact on their readability.

Table 5 Median scores for reader consultation: family carer (FC) information booklet ($N = 6$) & person with dementia (PwD) information booklet ($N = 11$)

Question	FC Median	FC Inter-quartile range	PwD median	PwD Inter-quartile range
Is the layout of the booklet easy to read?	4.5	3	4	2
Is it clear what the study is about?	5	1.25	4	2
Does it provide enough detail about the study to make an informed decision about whether or not to participate?	5	1.25	4	1
Is it clear as to what will happen to the participant at each stage of research?	5	1.25	4	2
Does it provide enough information about what the participant is committing to by consenting to take part?	5	0.50	4	2
Is it clear that the participants can withdraw from the study at any point without affecting the care they receive from health or social services or their legal rights?	5	0.25	5	0
Is it clear that if the participant does withdraw from the research interviews, they will no longer be able to receive any of the interventions?	5	0.50		
How would you rate the overall quality of the booklet?*	4.5	3.25	4	1.25

5-point Likert-type scale (1 = No, 3 = Partially, 5 = Yes).

*5-point Likert-type scale (1 = Low – serious or extensive shortcomings; 5 = High – minimal shortcomings).

Table 6 Flesch–Kincaid reading ease and grade level scores for consent documents

	Original		Post-reader consultation		Post-pilot	
	RE	GL	RE	GL	RE	GL
Recruitment leaflet	58.7	9.2	58.9	9.1	58.5	9.2
Family carer information booklet	58.8	10.4	61.5	9.7	61.6	9.6
Information booklet for people with memory problems	60.8	9.2	63.7	8.5	63.7	8.5

RE, Reading Ease; GL, Grade Level.

RE: higher scores = more readable.

GL: lower scores = more readable.

Discussion

Service users contributed to the development of the intervention in a unique way. The name of the intervention changed as a result of their input, and their personal experiences provided insight into the important elements of the Carer Supporter role, and in identifying important issues to address such as ‘off-loading’ as well as proposing practical ways to manage the matches to reduce its likelihood. Their vital contribution highlights the importance of involving service users in the development of complex interventions, particularly when the intervention itself relies on peer support.

The service users raised concerns about the inclusion of elements of the intervention, such as standard scripts, toolkits and sharing experiences. Again, this was important in making the intervention as appropriate and feasible as possible to the target recipients. Notably, the rejected methods were either ‘theory driven’ or attempted transfer from other countries through the scoping exercise. Researchers focused more on evidence-based practice but service users’ felt less comfortable with suggested innovations more congruent with their prevailing cultural norms. Such findings have important policy implications and lessons for the development of future peer support interventions.

Few people responded to the Round 2 Delphi questionnaire but the combined approach meant that service users were able to voice opinions, and concerns to the research team ensuring views were explored and contributing to a robust consensus removing the need for a third round. Service users, particularly current carers, often have heavy time constraints so achieved valid and effective involvement.

Feedback helped ensure the consent documents' suitability for their target audiences, and while the accessibility and acceptability of all materials improved, the grade level remained higher than recommended.²⁶ Complex interventions may be hard to convey simply, and including all necessary information may raise grade level and lower readability. Alternatively, it may be argued that the readers were not altogether representative of participant groups, being perhaps more educated or articulate. Members of the Uniting Carers network and the DeNDRoN Patient and Public Involvement Forum often participate in research activities and consultations and may be more used to reading information concerning research. Equally, we were unable to reach isolated carers who were the target participants for the intervention study.

Following reader consultations, these documents were used during the pilot trial of the intervention, and participants being consented into the trial suggested that the books remained difficult to understand in places. A second round of consultations did not take place after the materials had been amended, so it is difficult to know exactly how far the materials improved as a result of the consultations. However, post-pilot the readability of documents was similar to the readability of the documents post-consultation, perhaps reflecting a further issue with the Flesch–Kincaid formula only addressing one aspect of 'readability'. Indeed, the validity of these measures is debated, with Simplified Measure of Gobbledygook or Suitability Assessment of Materials suggested as preferable.²⁶ Many of the qualitative comments on materials focused on their visual impact, and the importance of spacing

and pictures, neither considered within Flesch–Kincaid.

A better approach for service user involvement in developing materials may be to combine service user consultation with piloting materials in the field. De Jong and Rijinks suggest that clarity and structure are raised in first consultation, but issues of credibility are raised in a second evaluation.²⁷ Focus groups with service users may have enabled ideas to be fully explored and misunderstandings addressed at the time through discussion. While these findings are based on public health information development, they may be valid for developing informed consent documents, emphasizing the importance of multiple rounds of consultation. Despite this, the current study demonstrated that consultation need only be small scale to generate changes.

Limitations and implications for service user involvement

The goal was for service users to feel more empowered apparently achieved for Study 1 where service users met face-to-face, but less so for Study 2 where they did not. Service users may prefer methods allowing them to debate ideas with others. Anonymized methods of contributing may be adequate and suitable for involving service users in research, who may have varying access to different levels of education and other resources. However, they assume comfort with the research process and may not suit all service users.

The consensus methods adopted were very structured, and although we intended to adopt a consultation model of involvement, some aspects may have reflected a more traditional research paradigm in which service users are only involved as participants or even as subjects. If so, service users may have lacked ownership of the process, perhaps limiting their contribution,²⁸ so that a more 'bottom up', less-structured approach may have been more generally appropriate.

The process may also have been improved by involving the same group of service users

for both methods. Over time, service users would gain knowledge about the intervention so making their contribution more meaningful. As well as improving the outcomes from a research perspective, on-going involvement, or prolonged engagement, has been of greater benefit to service users.^{5,29} Service users in the current study were not asked about their experiences of participation, which therefore represents an important dimension for future research. Actively and systematically seeking feedback from service users may have been useful to gauge whether they felt their contribution was meaningful, how far they felt empowered and to develop insight into how to improve the methodological approach.

Conclusions

Service users can be consulted about how to improve a research grant, research methodology or therapeutic intervention, but constraints on research processes and resources may explain why much service user involvement is consultative.³⁰ This study shows service users can be involved meaningfully through consultation while also highlighting the drawbacks of some methods.

Both consensus methods highlighted ways in which the intervention and documentation were adapted to incorporate users' perspectives through a consultation model approach. The intervention materials gained relevance and feasibility from sustained and discursive consultation with service users in their development. This increased the team's understanding of specific concerns faced by carers of people with dementia, vital for developing a meaningful peer support programme. Such consultation also flagged unexpected carers' concerns such as the potential burden placed on carers by Carer Supporters, which improved the acceptability of the final intervention, increasing its likely uptake and adherence. However, high acceptability may entail compromises in innovation. The intervention used in the SHIELD

CSP is a pragmatic evaluation of the kind of service currently provided within the UK voluntary and charitable sector. Enabling its wider availability to carers was an outcome of special concern to those service users involved in developing the SHIELD CSP intervention. Nonetheless, more knowledge is needed of how and how far different forms of consultation can successfully engage and empower service users.

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Conflict of interest

The authors declare no known conflict of interest.

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