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Research Article

A Core Outcome Set to Evaluate Physical Activity Interventions for People Living With Dementia

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Abstract

Background and Objectives: A core outcome set (COS) to evaluate physical activity (PA) interventions for people living with dementia is needed, as the development of guidelines is currently limited by important heterogeneity in this field of research. Development of COS often includes Delphi surveys, but people living with dementia are often excluded. This study aimed to reach consensus on this COS using a modified Delphi survey to enable the participation of people living with dementia.
Research Design and Methods: Two stakeholders groups took part in a Delphi survey (Group 1: people living with dementia and family caregivers; Group 2: professionals from different backgrounds, including physiotherapists, occupational therapists, and researchers). Caregivers and professionals completed the survey remotely. Participants living with dementia took part face-to-face, using a card sorting strategy. The consensus process was finalized with a consensus meeting.
Results: Ninety-five participants of both groups completed the modified Delphi. Of those, 11 attended the consensus meeting. The card sorting strategy was successful at including people living with dementia. Seven outcomes reached consensus: preventing falls; doing what you can do; staying healthy and fit; walking better, being able to stand up and climb stairs; feeling brighter; enjoying the moment; and, feeling useful and having a purpose.
Discussion and Implications: Robust and innovative methodological strategies were used to reach a consensus on a COS (what to measure) to evaluate PA for people living with dementia. Future work will focus on the selection of the most appropriate tools to measure these outcomes (how to measure).

Keywords: Exercise, Alzheimer's disease, What to measure, Delphi

Dementia is estimated to affect 46.8 million people worldwide (Alzheimer's Disease International, 2015). A progressive and debilitating disease, dementia impacts those living with the condition, their caregivers and health care providers (Alzheimer's Disease International, 2015; Pinzon et al., 2013; Reed et al., 2014). Physical activity (PA), defined by the World Health Organization as "any body movement produced by skeletal muscles that requires energy expenditure" is often recommended for people living with dementia (Miskovski, 2014; National Institute for Health and Care Excellence, 2006). Potential benefits include improvements in independence for functional activities of daily living, physical performance, and executive function (Forbes, Forbes, Blake, Thiessen, & Forbes, 2015; Ohman et al., 2016; Rao, Chou, Bursley, Smulofsky, & Jezequel, 2014). However, the precise impact of PA, including the ideal dose to maximize benefits for people living with dementia, is not yet known. Recent systematic reviews have reached limited conclusions due to heterogeneity in the selection and reporting of outcomes (Forbes et al., 2015; Rao et al., 2014). Consequently, no guidelines are currently available for PA in this population, and health professionals are limited in the advice they can provide. PA interventions are therefore not used to maximum benefit due to the lack of concrete guidance on ideal dose and expected outcomes. The development of a core outcome set (COS) for use in research evaluating PA interventions for people living with dementia has therefore been recommended (Gonçalves, Cruz, Marques, Demain, & Samuel, 2018).

A COS is an agreed minimum set of outcomes to be measured and reported in clinical trials of a particular health condition and/or intervention (Kirkham et al., 2016), with a view to allow studies to be comparable and fast-track guidance to practice. COS development has increased substantially in recent years across a wide range of conditions (Gargon et al., 2018). COS development includes a consensus process to agree which outcomes should be included (i.e., what to measure; Kirkham et al., 2016). Delphi surveys are commonly used by COS developers as a method to achieve consensus (Gargon et al., 2014), as they allow remote and anonymous participation from stakeholders (Keeney, Hasson, & McKenna, 2011). While multiple variations of the Delphi method have been reported in the literature, a Delphi always involves several survey rounds where participants are asked to score or rank a list of items, while receiving feedback on the scores of peers in previous rounds (Keeney et al., 2011; McMillan, King, & Tully, 2016). The inclusion of patients in COS development—in this case, people living with dementia—is considered vital, as they bring a unique perspective about living with the condition. If they are not included, the COS risks missing important outcomes relevant to patient care (Sinha, Smyth, & Williamson, 2011; Young & Bagley, 2016). People living with dementia experience a decline in cognitive function, affecting their ability to learn and retain new information as well as their ability to maintain attention levels, reason, judgment, and make decisions (Baudic et al., 2006; Capucho & Brucki, 2011; Lafleche & Albert, 1995; Storandt, 2008). They may therefore find it difficult to fully engage in a traditional Delphi survey, which may be why several previous Delphi surveys about aspects of dementia care did not include people living with dementia in their expert panels (Annear et al., 2015; Page, Potter, Clifford, McLachlan, & Etherton-Beer, 2015; Patterson, Newman, & Doona, 2016; Verkade et al., 2010).

The present study aimed to first reach consensus on a COS applicable to effectiveness trials and clinical practice to evaluate PA interventions in people living with dementia, across different stages of disease progression and activity settings. Second, it aimed to develop an innovative adaptation to the Delphi method, using a card sorting strategy, to ensure full participation of people living with dementia in the consensus process.

Methods

The development of this COS followed the standards for reporting COS provided by the Core Outcome Set-STAndards for Reporting (COS-STAR) statement (Kirkham et al., 2016) and this consensus study meets the agreed reporting guidelines for Delphi studies (Diamond et al., 2014; Sinha et al., 2011).

Registration and Ethical Approval

This COS was registered in the Core Outcome Measures in Effectiveness Trials initiative database (http://www.comet-initiative.org/studies/details/708?result=true) and was approved by the ethics committee at the Faculty of Environmental and Life Sciences, University of Southampton (ethics number: 19542). A protocol for the development of this COS, including this consensus phase, has been published elsewhere (Gonçalves, Marques, Demain, & Samuel, 2018). All included participants had capacity to consent to taking part in research at the time of data collection, and provided formal written consent.

Participants and Recruitment

Two stakeholder groups were considered key to the development of this COS.

Group 1: People living with dementia and their informal caregivers (relatives or friends) were recruited in the United Kingdom. Adverts and research information activities were conducted through gatekeepers of charities providing support to people living with dementia and their caregivers, and via the "Join Dementia Research" database. Potential participants were considered for inclusion if they contacted the research team expressing an interest in taking part.

Group 2: Professionals (e.g., physiotherapists, occupational therapists, nurses, formal caregivers, etc.) involved in the design or delivery of PA interventions for people living with dementia, in research and in practice, were also recruited. Professional organizations in different countries (e.g., universities, physiotherapy associations, dementia, and aging-related charities) disseminated information about this study and potential participants made contact with the research team, if interested in taking part.

The ideal sample size for a Delphi study has not been identified, with studies using sample sizes ranging from 5 to more than 1,000. However, Akins, Tolson, and Cole (2005) compared the response characteristics of an homogenous group of 23 participants against computer generated samples of 1,000 and 2,000 participants and found all responses to be stable, concluding that small and homogenous groups of Delphi participants (e.g., n = 23) can generate reliable responses (Akins et al., 2005). The present study aimed to include 40 participants in each stakeholder group. This was considered an appropriate number as while the group was homogeneous (all participants were required to have experience of PA in dementia as a person living with dementia or caregiver; or a professional) some intra-group variation was sought, to allow representation of all stages of dementia, a range of dementia types, professional backgrounds, and activity settings. A snowball recruitment strategy (Valerio et al., 2016) was used for both groups. In this recruitment strategy, participants were asked to share the link to the survey, and/or the contact details of the research team, with peers who may be interested in taking part. The use of this strategy meant that some participants may have been aware of the identity of some of their peers who were also part of the Delphi, making it a quasi-anonymized survey.

Inclusion and Exclusion Criteria

Group 1: Caregivers were included if they had current or previous experience of supporting someone living with dementia doing any form of PA, at any stage of their disease progression and in any setting. Caregivers included spouses, friends, or adult children. Those unable to understand written English were excluded.

People living with dementia were included if they had a known diagnosis of dementia (self-reported), capacity to consent to take part in research (assessed immediately before data collection and following guidance from the British Psychological Society; Dobson, 2008) and were able to communicate verbally in English. People living with dementia provided written consent before data collection, and verbal consent throughout data collection. They were included from three counties in the United Kingdom: Dorset, Hampshire, and Sussex. Those who had been bedridden since before the diagnosis or unable to complete the survey, due to their cognitive impairment, were excluded.

Group 2: Professionals were included if they had any experience in the design or delivery of any type of PA interventions for people living with dementia, in any stage or setting, and in any country in the world. Professionals were excluded if they were unable to understand written English.

Delphi Survey: Round 1

The first round of a Delphi survey traditionally consists of open ended questions, asking participants to generate an initial list of topics (in this case, outcome domains) to be agreed upon in subsequent survey rounds (Keeney et al., 2011). The present study used a modified Delphi approach: the 50 outcome domains (referred to as "outcomes") presented to participants in Round 1 of this Delphi survey were identified through a systematic literature review (Gonçalves, Cruz, et al., 2018) and a qualitative study previously conducted with both stakeholder groups (Gonçalves, Marques, Samuel, & Demain, 2019). Patient and public involvement consultations were critical to the design of this study. These identified that prioritization from such a long list (n = 50) would be too cognitively demanding for people with dementia, regardless of the method used to allow their participation. A decision was therefore taken to further modify the original Delphi method, that is, not include people living with dementia until Round 2, when the number of outcomes to be prioritized was reduced. This compromise was considered acceptable because people living with dementia had been pivot to the long list development through their participation in the qualitative study (Gonçalves et al., 2019).

In Round 1, participants (caregivers and professionals) completed the survey remotely, either online using SurveyGizmo software, or using a paper format, with prepaid envelopes distributed with the surveys. Consent was provided with the return of the surveys. The online and paper surveys were identical and prompted participants to select up to nine outcomes they considered most important, from the initial list of 50 outcomes. Participants were also asked to suggest any additional outcomes. The selection of up to nine outcomes was based on COS development recommendations to include no more than nine outcomes in the final COS, to promote its applicability (Boers et al., 2014). To minimize the length of the survey, participants were not asked to provide a justification for their choices. A glossary, with definitions for each of the outcomes was available with all surveys.

Delphi Survey: Round 2

In Round 2, the list of outcomes was presented in order from the most to the least frequently selected during Round 1. The percentage of all participants selecting each individual outcome was also shown. Each participant was reminded of the outcomes ($n \leq 9$) they had personally selected in Round 1. Participants from Round 1 were sent the survey for Round 2, in the same format they had used to complete Round 1 (either paper or online). A booklet providing more detailed results from Round 1, such as percentages of agreement per stakeholder group, and an updated glossary document (both available on request), were also made available with the Round 2 survey. Participants were asked to consider the results from Round 1 before reselecting the outcomes (up to nine) from this list they considered most important.

People living with dementia took part in Round 2, using a face-to-face card sorting strategy. The same principles described above for the Round 2 survey were followed. People living with dementia were shown the outcomes in order, from the most to the least frequently selected in Round 1, but instead of presenting the outcomes in a list format, the outcomes were presented as a pile of cards. Each card had a written and pictorial representation of one outcome. Participants living with dementia were asked to consider one card at a time, and decide if the outcome was “very important” or “not so important.” After going through the entire pile, the cards in the “not so important” pile were excluded and those in the “very important” pile were counted. If they were nine or less, the survey ended. If they were more than nine the same process was repeated, until a pile with nine or less outcomes was achieved. Flowcharts illustrating this process, and photographic examples of cards, can be found in Supplementary Material A. All face-to-face sessions were audio recorded and participants were asked to “think aloud” as they completed the task. In the same session, people living with dementia completed the Mini-Mental State Examination (MMSE) (Folsteins, Folsteina, & McHugh, 1975) and the Physical Activity Scale for the Elderly (Washburn, Smith, Jette, & Janney, 1993), with support from a caregiver, for purposes of sample characterization only.

Selection of Outcomes and Definition of Consensus

Consensus was defined a priori, as previously published in the study protocol (Gonçalves, Marques, et al., 2018). At the end of Round 1, outcomes selected by ≤15% of all participants were eliminated except for those that had been mentioned by a person living with dementia during the qualitative study that informed the list of outcomes in Round 1 (Gonçalves et al., 2019). This exception ensured that outcomes potentially relevant to those living with dementia were not inadvertently excluded during Round 1, in which only professionals and caregivers participated.

After Round 2, outcomes selected as one of the top nine priorities by ≥70% *of all participants* or ≥80% of participants of *one stakeholder group* were included, without further discussion, in the final COS. Outcomes selected by ≤15% of all participants were permanently excluded. Any remaining outcomes (voted between 16% and 69% of all participants) were taken for further discussion at a consensus meeting. At the consensus meeting only outcomes with a minimum agreement of 90% were include in the final COS (Gonçalves, Marques, et al., 2018).

Consensus Meeting

Patient and public representatives advised on a sample size of up to 15, so that the meeting remained dementia friendly. To minimize bias in the selection of participants attending the consensus meeting whilst also controlling the sample size, all Round 2 survey participants living within a 60 mile radius of the meeting venue, and that were not housebound, were invited to attend. Potential participants were sent the results of the Delphi Round 2 alongside their invitation to the consensus meeting. Invitations were sent out 3 weeks before the meeting and a reminder sent to nonrespondents 1 week before the meeting. Purposive sampling was used to ensure both groups were represented, as well as more than one activity setting, and more than one stage of disease progression.

The meeting was facilitated by the first author, who prompted both groups to present arguments toward the inclusion or exclusion of each of the outcomes. The discussion on each outcome was followed by a vote. In the voting of each outcome, participants were asked to raise their hand if they wanted to include the outcome that had just been discussed. The meeting was audio recorded.

Patient and Public Involvement

This study benefited from close advice of a caregiver research partner and coauthor (M. Ramsay). She was involved in the recruitment, design of participant documentation, revision of the Delphi survey before it was distributed and planning of the consensus meeting, to ensure full participation from people living with dementia and their caregivers. Additional patient and public involvement was used in the following activities:

- Use of lay terminology during the Delphi:

A caregiver, a professional who is also a family caregiver, and a member of a dementia-related charity were involved in the process of renaming the outcomes into lay terms, before they were used in the Delphi Round 1. They also advised on the glossary that accompanied the Delphi surveys.

- Design of the cards for the card sorting strategy:

A patient support group and two caregivers’ groups were consulted during the design of the cards used by people living with dementia in the Delphi Round 2. Design advice consisted of: the size of the cards (15 cm × 10 cm), the use of pale yellow as a background color for the cards, the use of photographs of people (rather than icons), and not using photographs with background (e.g., one person shopping with a shopping trolley, but without a busy shop as a background). Advice was also received on showing only one card at a time to participants living with dementia.

Results

Delphi Participants’ Characteristics

In Round 1, a total of 44 caregivers (14 male) and 47 professionals (10 male) completed the survey. Of those, 82% of the caregivers (*n* = 36; 12 male) and 83% of professionals (*n* = 39; 10 male) also completed Round 2. A total of 20 people living with dementia (10 male; with MMSE scores ranging from 9 to 28; mean score: 21.1 ± 5.3) joined the Round 2 survey. See Table 1 for detailed demographic characterization of all participants in Round 2.

Usability of the Card Sorting Strategy

The card sorting strategy was feasible for enabling people living with dementia to prioritize outcomes. Only one person

Table 1. Characteristics of Participants Who Completed the Delphi Round 2

Group 1: People living with dementia and family caregivers (*n* = 56)	Mean (*SD*) or *n* (%)	Group 2: Professionals (*n* = 39)	Mean (*SD*) or *n* (%)
Role		Role	
People living with dementia	20 (35.7%)	Physiotherapists	14 (35.9%)
Family caregivers	36 (64.3%)	Occupational therapists	6 (15.4%)
		Rehabilitation assistants	4 (10.3%)
		Nurses	1 (2.6%)
		Members of charities or volunteer organizations	7 (17.9%)
		Social workers	1 (2.6%)
		Health care support workers	1 (2.6%)
		Academics	8 (20.5%)
Demographics			
Age (years)			
18–29	1 (1.8%)	18–29	8 (20.5%)
30–39	0 (0%)	30–39	9 (23.1%)
40–49	2 (3.6%)	40–49	6 (15.4%)
50–59	12 (21.4%)	50–59	12 (30.8%)
60–69	10 (17.9%)	60–69	3 (7.7%)
70–79	18 (32.1%)	70–79	1 (2.6%)
80–89	7 (12.5%)	80–89	
90–99	6 (10.7%)	90–99	
Gender (female)	34 (60.7%)		29 (74.4%)
Years post diagnosis	6.1 (±4.1)	Years of experience in dementia care	9.1 (±6.3)
Physical Activity Scale for the elderly (people living with dementia only)	52.0 (±45.1)		
Living with or supporting people living the following dementia types (self-reported)			
Alzheimer's disease	23 (41.1%)		
Vascular dementia	8 (14.3%)		
Mixed dementia	16 (28.6%)		
Dementia with Lewy bodies	2 (3.6%)		
Frontotemporal dementia	1 (1.8%)		
Not known	6 (10.7%)		
Experience of doing or supporting PA per stage of disease progression (self-reported by caregivers and according to Mini-Mental stage examination score for people living with dementia)		Experience of supporting PA for people living with dementia per stage of disease progression	
Mild to moderate	27 (48.2%)	Mild to moderate	8 (20.5%)
Moderate to severe	16 (28.5%)	Moderate to severe	7 (17.9%)
Severe	1 (1.8%)	Severe	2 (5.1%)
All stages	11 (19.6%)	All stages	26 (66.7%)
Not known	2 (3.6%)	Not known	0 (0%)
Mini-Mental state examination scores (people living with dementia only)	21.1 (±5.3)		
Experience of doing or supporting PA per setting		Experience of supporting PA per setting	
Home or other community settings	52 (92.9%)	Home or other community settings	35 (89.7%)
Sheltered accommodation	6 (10.7%)	Sheltered accommodation	8 (20.5%)
Care or nursing home or assisted living	18 (32.1%)	Care or nursing home or assisted living	22 (56.4%)
Hospital	2 (3.6%)	Hospital	24 (61.5%)

Note. PA, physical activity. Please note that one participant may have supported people living with dementia in multiple settings and stages of disease progression. A total of 44 caregivers and 47 professionals had completed the previous round of the Delphi survey.

living with dementia (MMSE score: 19) was excluded for not being able to complete the card sorting task. The session audio-recordings showed that participants were making thoughtful choices and fully understood the process of sorting the cards, as illustrated in the quotes below.

Participant number 8 (male, living with dementia at home, MMSE score: 27), mentioned how he found the process easy to understand. He was also always aware that the goal was to reduce the pile of cards to up to nine:

> ACG: We are going to organize them [cards] into "very important" and "not so important". P8—"So we will make a pile." ACG: "yes, that's right". P8: I see, this is very high tech research [laughing]. Well, I like it. I can understand it. P8: Well, I am a one vote man [referring to be putting all first five cards on the "very important pile"]. But I understand this is not a practical situation because at some point I will have to choose.

Participant 11 (male, living in a care home, MMSE score: 11), found it difficult to read the cards accurately, but when the cards were read to him, he would carefully weigh his decision of whether to include or exclude an outcome.

> ACG, showing and reading the card: "feeling less depressed and avoiding depression." P11: "That is definitely on my top nine." ACG: "Ok. What about this one "slowing down the dementia." P11: "can we put that on the side before I decide on that one?" ACG: "that's a good plan."

Participants also often referred to their own experiences and preferences while selecting outcomes, demonstrating that their choices were meaningful and well thought through.

> Feeling useful and having a purpose. Well, I like to feel useful, so that is very important [to me]. (Participant 17, female, living in assisted living accommodation, MMSE score: 22)

All participants were able to complete the task without help from their caregivers (although in some cases participants felt reassured by the presence of a relative or friend during the session). On average, each face-to-face card sorting session took 30 min, ranging from 17 to 43 min.

Consensus Meeting: Characteristics of the Expert Panel

Of those who completed Round 2, 69 participants (37 caregivers, 18 people living with dementia and 14 professionals) met the inclusion criteria and were invited to attend the consensus meeting. A total of 11 participants were available to take part on the selected date. Among those who attended the meeting, seven were caregivers (two male, five had experience of supporting someone living with dementia at home, or in sheltered accommodation, and four in a care home setting); one person living with dementia, supported by her husband (living in their own home) and three health care professionals (all female, one nurse, one occupational therapist, and one rehabilitation assistant, with experience of supporting people living with dementia in community and in hospital settings). The 11 participants self-declared having experience of living with, or supporting people living with all stages of dementia progression and a variety of dementia types, including Alzheimer's disease ($n = 4$), dementia with Lewy bodies ($n = 2$), mixed dementia ($n = 2$), and vascular dementia ($n = 1$).

Selection of Outcomes and Recommendations from the Expert Panel at the Consensus Meeting

The process of selection of outcomes from Delphi Round 1 through to the consensus meeting is illustrated in Figure 1. The list of all outcomes considered in both Delphi rounds and the consensus meeting is available in Supplementary Material B. At the end of Round 2 of the Delphi survey, 31 of the 50 outcomes had been selected by less than 15% of all participants and were therefore excluded. However, none of the outcomes met the criteria to be directly included in the COS without further discussion (selected by ≥70% of all participants or ≥80% of participants of one group). Thus, all remaining outcomes ($n = 19$) were discussed at the consensus meeting. Consultation with members of patient and public group revealed that a consensus meeting including the discussion of 19 outcomes would be feasible. At the consensus meeting, a total of seven outcomes met the definition of consensus and were included in the final COS: preventing falls; doing what you can do; staying healthy and fit; walking better, being able to stand up and climb stairs; feeling brighter; enjoying the moment; and feeling useful and having a purpose. Table 2 presents further details on these seven outcomes, including definitions and the

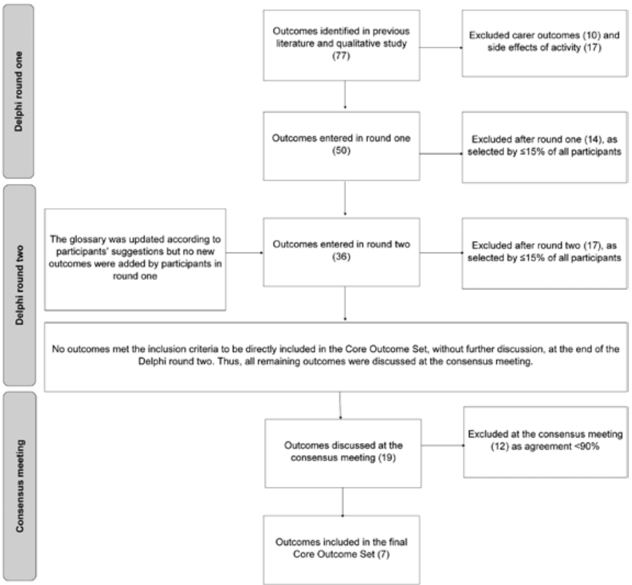

Figure 1. Flowchart of the development of final core outcome set (COS) to evaluate physical activity (PA) in people living with dementia.

breakdown of the percentages of agreement per participant group and per stakeholder within each group. In addition to these seven outcomes, participants at the consensus meeting also felt the need to make two specific recommendations for intervention delivery. See Table 2 for further details.

Table 2. Core Outcome Set (COS) to Evaluate Physical Activity (PA) Interventions for People Living With Dementia

Outcome in lay terms included in the final COS	Definition, as in the glossary made available to the Delphi participants, and with corrections made by the expert panel at the consensus meeting	Percentage of agreement: Delphi Round 2
Preventing falls	Number of fallers; number of falls; number of falls sustained by one person living with dementia; health care costs associated with managing fall related injuries (e.g., fractures); falls risk, including balance and fear of falling.	All participants: 67.4% Group 1: 62.5% Caregivers: 63.9% People with dementia: 60% Group 2 (professionals): 74.4%
Walking better, being able to stand up and climb stairs	Keeping mobile or regaining mobility; keeping moving; being more mobile indoors and outdoors; standing up and walking up and down. Climbing stairs. Includes all aspects of gait, using less supportive walking aids and keeping the ability to change position and keeping movement in the joints.	All participants: 56.8% Group 1: 51.8% Caregivers: 63.9% People with dementia: 30% Group 2 (professionals): 61.4%
Staying healthy and fit	Overall health, general ability or performance. Being fit, strong and ready for activity. Staying well and having less medical diagnoses.	All participants: 25.3% Group 1: 19.4% Caregivers: 39.3% People with dementia: 75% Group 2 (professionals): 5.1%
Doing what you can do	Using one's physical being. Using all available skills and abilities. Expressing a physical self. Seeking movement as a routine part of life.	All participants: 17.9% Group 1: 23.2% Caregivers: 16.7% People with dementia: 35% Group 2 (professionals): 10.3%
Feeling useful and having a purpose	Feeling useful and having a role or purpose. Sense of belonging and of being included. Being part of a family, team, or a group. Being a volunteer. Helping family, neighbors, and peers. Being occupied with meaningful activity. Doing what one is passionate about and having something to look forward to.	All participants: 51.6% Group 1: 44.6% Caregivers: 44.4% People with dementia: 45% Group 2 (professionals): 61.5%
Feeling brighter	Lifting mood or being in good mood; also referred to as "improving mood levels," feeling content, bright, and happy or having fun. Having a positive attitude. Showing fewer negative emotions. Note: To be measured immediately post activity.	All participants: 18.9% Group 1: 21.4% Caregivers: 22.2% People with dementia: 20% Group 2 (professionals): 15.4%
Enjoying the moment	Being anchored to the present by activity. Learning or doing something new. Living in the moment. Having an adventure. Not having to think about anything else. Note: To be measured during activity.	All participants: 38.9% Group 1: 33.9% Caregivers: 50% People with dementia: 5% Group 2 (professionals): 46.2%
Additional recommendations by the expert panel at the consensus meeting:		
Seeing the person, not the dementia	Although not voted as a core outcome of PA, the panel recommended that all activities should be designed and delivered based on the principle that people living with dementia are seen as people and not a diagnosis, and interventions should be tailored to the individual, who should be always seen as person.	
Reducing anxiety	Reducing anxiety was not voted as a potential benefit of PA, but the panel recommended it should be measured as a potential side effect. Activities should focus on improving the mood of the person living with dementia ("feeling brighter") but "anxiety" should be monitored as a counterweight. It is accepted that an activity will not necessarily make "everyone feel brighter" and therefore it is important to monitor and report on possible increases in anxiety to weigh up the benefit of the activity on mood.	

Note. At the consensus meeting, the percentage of agreement was 100% to all the outcomes included in this final COS. COS, core outcome set; PA, physical activity.

Discussion

This is the first study to identify a COS to evaluate PA interventions for people living with dementia, across activity settings and different stages of disease progression. A novel card sorting strategy was found to be feasible to include people living with dementia in the consensus process. Through the use of this innovative approach, people living with dementia, joined caregivers and professionals to reach consensus on seven outcomes: preventing falls; doing what you can do; staying healthy and fit; walking better, being able to stand up and climb stairs; feeling brighter; enjoying the moment; and feeling useful and having a purpose (see definitions in Table 2).

"Staying healthy and fit" is a good example of the positive impact of the inclusion of patients in this COS. During the Delphi, this outcome was selected by 5% of the professionals and a contrasting 75% of people living with dementia. At the consensus meeting, the views of those with dementia were honored and participants were unanimous on the inclusion of this outcome in the final COS. This is a key example, to add to others provided in the literature (Hewlett et al., 2005; Mease et al., 2008) of the importance of including patients in the development of COS.

Other COS, relating to a wide range of pathologies, often reach consensus on the outcome: "quality of life" (Allin et al., 2017; Haywood, Griffin, Achten, & Costa, 2014; Potter, Holcombe, Ward, Blazeby, & BRAVO Steering Group, 2015; Sinha, Gallagher, Williamson, & Smyth, 2012). Quality of life is also known to be an important outcome for people living with dementia. However, previous literature has identified that people living with dementia particularly value specific constructs within the broader category of quality of life, such as the concept of "feeling useful" (de Boer et al., 2007). In line with these findings, the present COS includes three specific and nonoverlapping outcomes, related to quality of life, but not "quality of life" as whole: "Feeling useful and having a purpose," "Enjoying the moment," and "Feeling brighter." The selection of these specific outcomes shows how the present COS represents what truly matters to patients, as well as to those who care for them.

Clinicians may also be aware of the International Consortium of Health Outcome Measurement (ICHOM), which has produced a Standard Set of outcomes for dementia care (International Consortium for Health Outcomes Measurement, 2017). Standard Sets by ICHOM are sets of outcomes, encouraged to be reported in routine health care provision worldwide, allowing clinicians to collect data on the same outcomes and benchmark the services they provide. The ICHOM Standard Set for dementia includes the outcome "falls," which is also an outcome included in this COS to evaluate PA. Therefore, if this COS is implemented in both research and clinical practice, as planned, professionals delivering PA interventions in clinical practice will be able to benchmark their intervention outcomes against not only research outcomes, but also other health care providers internationally.

The standard set provided by ICHOM also includes the outcome "Functional abilities and independence." This outcome was also identified as the most frequently reported in research published in the last decade about physical activity for people living with dementia (Gonçalves, Cruz, et al., 2018). However, "functional activities and independence" did not reach consensus in the present study. "Functional activities and independence" is a very broad outcome, including independence for basic activities of daily living such as personal hygiene, dressing, completing transfers and mobility, but also instrumental and more complex tasks such as managing finances (Mlinac & Feng, 2016). It is possible that within the specific context of PA, functional independence aspects specifically related to mobility (included in the present COS as "walking better, being able to stand up and climb stairs") are more relevant. For instance, exercise is a well-established intervention for rehabilitation post hip fracture (Beaupre et al., 2013) and the COS for hip fracture trials, includes "mobility" as an outcome (Haywood et al., 2014). Thus, "mobility" may be a specific outcome of functional independence, possibly more relevant with regard to PA interventions.

Strengths and Limitations

The development of this COS used innovative and robust methods of consensus and followed a pre-defined level of consensus. It also benefited from patient and public involvement and meaningful participation of people living with dementia in the consensus process, which is considered a priority in COS development (Sinha et al., 2011; Young & Bagley, 2016). This consensus study included a Delphi survey. Delphi surveys are known to face challenges with regards to low response rates (Keeney et al., 2011). Other published COS report Delphi surveys with variable attrition rates between Rounds 1 and 2, ranging from 2% (McGrattan et al., 2018) to 50% (Chiarotto et al., 2015). Thus, the present study describes a two-round Delphi survey with low attrition rate between rounds, followed by a consensus meeting with meaningful and in-depth participation of both groups of stakeholders. The card sorting strategy described here as a Delphi adaptation provides future researchers in this field with a possible tool to enable prioritization and decision making by people living with dementia. By enabling full participation of people living with dementia in defining their own priorities, this card sorting strategy is also in line with the current national and international agenda to give people living with dementia the opportunity to take part in research and actively influence their care (Curry, 2017; Department of Health, 2015).

Some limitations need to be acknowledged. The card sort-sorting strategy was developed to be as similar as possible to the remote survey completed by professionals and caregivers. However, the two approaches were not exactly the same. The card sorting strategy involves considering one outcome at a time (in contrast to seeing the whole list of outcomes). It also involved one-to-one interaction with the researcher. Future methodological research is recommended to compare results obtained from a card-sorting strategy with the remote version of the survey with caregivers and professionals. Only one person living with dementia was at the consensus meeting. All efforts were made to enable the participation of more people living with dementia, however reasons such as caring responsibilities, transport, decline in cognitive abilities since the Delphi Round 2 and stigma of talking about living with dementia in public meant that all other participants living with dementia declined the invitation to take part. To overcome this limitation, some of the caregivers discussed the results booklet that had been sent with the invitation with their relative/friend with dementia before attending the consensus meeting, and used this information to inform their voting at the meeting.

This COS also had only limited representation from international stakeholders. While this may be seen as a limitation, it was an active choice to prioritize resources on the meaningful inclusion of people living with dementia and their caregivers, rather than the inclusion of an extensive international group of experts. Evidence is available for the need to include patients in COS (Hewlett et al., 2005), yet to our knowledge, no previous studies have ascertained if a COS would be different or have a stronger uptake if developed internationally. Therefore, further work may be necessary to determine if this COS is applicable outside the United Kingdom.

Implications for Policy, Research, and Practice

The seven outcomes agreed to be core in physical activity interventions for people living with dementia can be used to guide the design and promotion of PA in this population, by clinicians, researchers, and policy makers. For instance, the inclusion of elements of PA that can improve walking, standing, and stairs and reduce falls are worth including.

The card sorting strategy presented in the current study can be used in future research, policy and practice, to help gather views and priorities of people living with dementia. Examples of the use of this strategy include consulting people living with dementia to determine the primary outcome of a research intervention, involving people living with dementia in setting research priorities in dementia care, and designing individual and person-centered care plans in clinical practice.

Conclusion

This innovative, robust, and inclusive methodological approach has identified a COS of the outcomes that should be measured to determine the effectiveness of all PA interventions in people living with dementia, in research and clinical practice. This COS is designed for all types of dementia, at any stage of the disease and in hospital, community and care home settings. The seven outcomes identified by people with dementia, their informal caregivers and professionals to be included as a minimum were: preventing falls; doing what you can do; staying healthy and fit; walking better, being able to stand up and climb stairs; feeling brighter; enjoying the moment; feeling useful and having a purpose. Future work will include the identification of measurement tools for this set of outcomes (i.e., how to measure). A card sorting method, designed with robust patient and public consultation, successfully enabled the full participation of people living with dementia in the selection and prioritization of meaningful outcomes.

Supplementary Material

Supplementary data are available at *The Gerontologist* online.

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Conflicts of Interest

None reported.

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