1	Outcomes	of Physical	Activity for	People L	iving with	Dementia:
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2 Qualitative Study to Inform a Core Outcome Set

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41 Abstract

Background: The need for a Core Outcome Set to evaluate physical activity interventions for people living with dementia, across stages of disease and intervention settings has been established. This qualitative study precedes the consensus phase of developing this Core Outcome Set and aims to: (i) compare the outcomes identified by patients, carers and professionals to those previously reported in the literature; (ii) and understand "why" certain outcomes are considered important.

47 Design and Methods: In-depth semi-structured interviews were conducted with people living with 48 dementia, family carers and professionals (n=29). The outcomes identified in the interviews were 49 mapped to a list of outcomes reported in a recent literature review. An in-depth thematic analysis was 50 conducted to understand the importance of physical activity in dementia care.

Results: A comprehensive, inductively derived list of 77 outcomes, common across stages of dementia and intervention setting, was put together for the consensus phase of this Core Outcome Set: ten of these were new outcomes generated by this qualitative study. Five themes explained why stakeholders perceived physical activity outcomes as important for people living with dementia: "being well and staying well", "having a role towards others", "maintaining identity", "being connected to the present" and "delivering good quality care".

57 Conclusion: Ten new outcomes of physical activity, not previously reported in recent literature, were
58 identified. Physical activity is considered important to people living with dementia due to its positive
59 impact on multiple health outcomes for both patients and carers.

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61 Contribution of the paper:

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• Qualitative methods ensure relevant outcomes are not missed in Core Outcome Sets.

Physical activity can enable a constant adaptation of self-identity to patients and carers as the
 dementia progresses and may bring positive outcomes to those living with severe dementia
 and/or comorbidities.

Physical activity for people living with dementia is linked to good quality care, overall wellness,
living in the present and being connected with others.

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69 Key Words: Physical activity; Dementia; Core Outcome Set; Qualitative study.

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71 Introduction

72 Dementia is a major cause of dependency and disability among older people, resulting in increased burden on individuals, carers and health care services [1]. The need for research into 73 74 interventions to improve care of people living with dementia is evident [2]. Physical activity, defined by the World Health Organization as "any bodily movement produced by skeletal muscles that requires 75 76 energy expenditure", may be one such intervention. Despite the large number of available studies, 77 guidance on the ideal dose of physical activity for people living with dementia is lacking. A recent literature review [3] identified substantial heterogeneity of outcomes reported in physical activity 78 research for people living with dementia. This is one factor limiting meta-analyses and the 79 80 establishment of robust conclusions in this field. The development of a Core Outcome Set – a minimum 81 set of outcomes to be measured across trials of a particular intervention and/or health condition [4] – 82 has therefore been recommended for physical activity interventions for people with dementia [3]. This 83 Core Outcome Set has been designed to be applicable across stages of disease progression and 84 intervention settings [3] to maximise homogeneity in this field of research, knowing that specific 85 outcomes for different stages of disease, types of dementia or activity settings can still be measured by 86 researchers, in addition to those recommended by the Core Outcome Set [4].

A gold standard for Core Outcome Set development is yet to be defined. The inclusion of qualitative methods preceding the consensus phase of COS development, represents a methodological innovation considered particularly necessary when research in the field of the Core Outcome Set lacks sufficient qualitative work [5]. Most qualitative studies about physical activity for people with dementia are linked to a specific intervention and are aimed at exploring feasibility, barriers and facilitators to that intervention [6-10]. The few available qualitative papers, not linked to a specific intervention, include only care home settings [11, 12] or people living with early stages of dementia [13, 14] and do not meet the needs of a Core Outcome Set applicable across intervention settings, types of dementia
and stages of the condition. Furthermore, these qualitative studies are not centred on intervention
outcomes, and therefore many outcomes, relevant to participants, may have been missed during data
collection.

98 Views of multiple stakeholders - patients, carers and professionals - may facilitate the selection
99 of meaningful outcomes for this Core Outcome Set, leading to the implementation of tailored
100 interventions, in research and clinical practice, as recommended in dementia research and policy [15].

101 The present qualitative study aimed to inform the next stage (a consensus study) of a Core 102 Outcome Set to evaluate physical activity interventions for people with dementia by (i) comparing the 103 outcomes identified by professionals, carers and patients against those previously described in the 104 literature and (ii) gaining a deeper understanding of "why" certain outcomes are considered important 105 in dementia care.

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107 **Design and Methods**

108 The present study was reported according to the consolidated criteria for reporting qualitative109 research (COREQ) [16].

110 Registration and Ethical Approval

This study is part of the development of a Core Outcome Set, registered with the Core Outcome
Measures in Effectiveness Trials initiative¹. Ethical approval was obtained from the ethics committee
at the Faculty Health Sciences, University of Southampton (ethics number: 19524). All participants
provided informed consent prior to taking part in this study.

115 Recruitment and Patient and Public Involvement

¹ http://www.comet-initiative.org/studies/details/708?result=true

116 Recruitment visits were made to support groups, exercise groups and dementia related activities and events. Posters were made available in public spaces (e.g. libraries, churches, social centres) and 117 flyers distributed via gatekeepers in charities and support groups. The study poster and a short 118 description of this research was made available through websites and newsletters of professional 119 120 organisations. Participants interested in taking part contacted the research team using the contact details 121 provided on posters and flyers. Information about the study was provided to potential participants (verbally and in a writing via the participant information sheet). A date for interview was only arranged 122 123 with those who wanted to participate. A phone call was made the day before the interview to offer any further clarifications and confirm the interview date. Formal consent was recorded on the day of the 124 125 interview.

This study benefited from patient and public involvement during recruitment and data analysis. A former carer of a person living with dementia, who also had a role as a leader in a carer support group, assisted the team to identify local dementia services and advised on strategies to approach gatekeepers in those organisations. This strategy had a very positive impact on recruitment for this study. She also contributed to the data analysis, by discussing findings with the authors as analysis progressed.

131

132 Inclusion criteria

- 133 The following participants were included:
- People with a diagnosis of dementia, with capacity to consent to take part in research
 at the time of data collection and able to communicate verbally in English;
- Family members who were currently involved or had previously been involved in the
 care of a relative living with dementia;
- Professionals who have been involved in promoting, designing or supporting physical
 activity for people with dementia.

141 Exclusion criteria

People with dementia were excluded if they had been bedridden since before the diagnosis. Family members were excluded if they were not in contact with the person with dementia since their diagnosis. Professionals were excluded if their professional role in dementia care was undertaken exclusively outside of the United Kingdom. Exclusion criteria were discussed with those who expressed an interest in taking part.

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148 Sampling

Purposive sampling was used, aiming for a maximum variation strategy [17] across stakeholdergroups, using the following criteria:

Stage of disease progression, determined by the Mini-Mental State Examination score,
completed by the first author (ACG - interviewer) immediately prior to the interview: "Mild to
moderate" – 17 to 26; "Moderate to severe" - 10 to 16 and "Severe" – less than 10 [18];

154 • Type of dementia;

• Activity setting (i.e. community, care or nursing homes, assisted living; hospital);

• Levels of physical activity, determined by the score on the Physical Activity Scale for the Elderly [19], completed immediately before the interview, with input from the carer; Scores range from zero (no physical activity completed in the previous seven days) to 693.9 (maximum physical activity level score);

Socioeconomic deprivation, determined by the Index of Multiple Deprivation [20], using the
 participants' post code, with scores ranging from 1 (most deprived) to 10 (least deprived).

162 Recruitment aimed to reach data saturation, which was defined as the point where new data163 being collected made little or no difference to the codes being generated from the data analysis [21].

164

165 Data collection

In-depth semi-structured interviews were conducted and audio-recorded by the first author [ACG], a female clinical doctoral research fellow and physiotherapist with previous experience of conducting qualitative studies and, at the time of data collection, was a senior clinician in an Older Person's Mental Health in-patient service, including a dementia ward. Participants were aware of the professional background of the interviewer. Reflective notes were written after each interview.

The interview topic guide was designed to enable participants to discuss outcomes of physical 171 activity and explore the importance of such outcomes. Professionals and carers were interviewed face-172 to-face or remotely (via telephone or video call), according to their preference. People living with 173 174 dementia were interviewed face-to-face, in a private venue of their choice, and encouraged to have a relative or friend with them at all times. During the interviews with people living with dementia, the 175 following strategies were used, based on previous research [22], and the interviewer's [ACG] 176 experience of communicating with people with living with dementia: asking simple questions, giving 177 178 time for the person to answer, rephrasing the question with help from the carer, maintaining good eve contact, reading body language for signs of fatigue or distress, offering breaks and choosing the time 179 and venue for the interview according to the person's needs. These strategies also facilitated the capacity 180 181 assessment. Capacity to consent to research was assessed based on the British Psychological Society 182 guidance [23]. When present, the carer helped the researcher to explain the study to the person with 183 dementia, providing all possible opportunities to make an informed decision. Carers were also 184 encouraged to note any signs of discomfort or distress, which may indicate the need to stop the interview.

185

186 Data analysis

To address the aims of this study, two separate types of analysis were completed. Both analysis'
steps were completed predominantly by the first author, with regular guidance and in consultation with
other authors.

Aim 1: Interviews were transcribed verbatim and analysed thematically [24]. The transcripts
were not returned to the participants for comments or corrections. Initial inductive (data driven) and

192 semantic codes (close to the participants' own words) were used across the data set, to identify potential outcomes of physical activity. An outcome was defined as "a perceived consequence or impact, positive 193 or negative, for people living with dementia, their carers or health services, whether intended or 194 incidental, arising from undertaking physical activity". Codes with equivalent semantic meanings were 195 196 merged and grouped into higher level codes (outcome domains). At this stage, a deductive approach 197 was used, and the outcome domains were compared, by two independent researchers [ACG and a researcher independent from this research team], against the outcome domains previously reported in 198 199 the literature [3]. A merged final list of outcome domains was created and the scope of each outcome domain defined. 200

Aim 2: Outcome domains were thematically organised, by identifying patterns and connections between outcomes that could be described by a higher level theme [24]. Each theme represented a meaningful concept to answer the question: "why is physical activity important to people living with dementia?" The final data analysis was presented back to four participants for member checking [25].

205

206 **Results**

207 Participant Characteristics

208 Interviews were conducted with 29 participants (5 people living with dementia; 14 carers and 10 professionals). The average interview duration was 67 minutes, ranging from 35 to 101 minutes. 209 210 Table 1 describes the sample characteristics. Previous research suggests that interviews involving 211 people in severe stages of dementia can be triangulated with interviews of their carers [26]. When it was not possible to gather the views of the person living with dementia, the carer was interviewed 212 213 instead, aiming to get as close as possible to the views of those at the later stages of dementia. In this 214 study, nine of the carers interviewed, were carers of people living with severe dementia and/or people 215 with dementia who were unable to communicate verbally or provide consent.

217 Aim 1: Comparing outcome domains generated by this study, against those found in the literature.

218 A final list of 77 outcome domains (60 positive/beneficial) was generated. Figure 1 illustrates the process of defining this list of outcome domains. Of the final 77 outcome domains, 10 (8 219 220 positive/beneficial) were new outcomes generated by this qualitative study and not reported in the 221 literature; nine (4 positive/beneficial) had been identified previously but were not mentioned by 222 participants in this study. Tables 2a and 2b highlight these outcome domains presented per stakeholder group, stage of disease progression and activity setting. An extended version of these tables including 223 all 77 outcome domains, which will be considered in the consensus phase, can be found in 224 225 supplementary material.

Most outcome domains (69 out of 77) were reported by both stakeholder groups, in multiple settings and dementia stages (Tables 2a, 2b and supplementary material). Data saturation was reached in both stakeholder groups, with no new outcome domains being generated by the last professional interview and only two new outcomes generated in the last patient/carer interview.

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232 Aim 2: Understanding why physical activity is important

Five core themes explained the importance of physical activity. All themes were described across stages of disease, intervention settings, and incorporated the views of both stakeholder groups (professionals and patients/carers). There were no opposing views between stakeholders. The generated themes are described below.

237

238 Being well and staying well

Participants across all stakeholder groups reported using physical activity to improve or
 maintain multiple aspects of health and wellbeing of the person living with dementia, keeping an overall
 state of wellness - physical, cognitive and emotional - despite the diagnosis of dementia.

242 "Mental and physical health. I mean as a starting, as a baseline point. You are better, you are
243 in better health, the more you get to do it. (...) Well, I mean physical stamina, strength, these things
244 support everything. Body and mind are connected. (...) It is promoting health. It promotes health across
245 the board." Occupational therapist (All stages - Care homes).

246 "It gets me out of my routine, because (...) if I was at home, and things like that, it would drive
247 me up the wall." Person living with dementia (mild to moderate stages – home).

The data demonstrated that potential positive health benefits of physical activity for people living with dementia are often influenced by other factors: participants weighed up the benefits against the burden that physical activity may generate for people living with dementia; and the extent to which supporting physical activity was beneficial or detrimental to carers. All stakeholder groups also expressed concerns about the potential for increased physical activity increasing the risk of falls:

253 "ACG: would anything stop you from walking? Participant: NO! No. (...) Unless you fall flat
254 on your face." Person living with dementia (Moderate to severe stages – home)

The negative effects or burden of physical activity were not only related to accidents and injuries but also to a range of emotional and behavioural negative effects, such as becoming agitated or distressed, feeling exhausted or not being able to sleep after the activity.

"ACG: You said you stopped the ball game because (...) she was aggressive..." Participant:
"It wasn't an aggression as in it didn't cause harm to anyone, but the way she was kicking. It was a bit
forceful, with quite a grimaced face so that would demonstrate to me that she wasn't particularly happy
about this task." Occupational Therapist (All stages – Hospital).

- Carers also reported on the burden of supporting activity: increased workload from keeping the person living with dementia active, while managing their own health; and perceived negative emotions associated with the activity, such as responsibility, boredom, guilt and worry.
- 265 "To be honest I think it was like a tedious kind of thing to do [walking with her mother up and
 266 down the corridor] because it was very slow and... I mean but it did feel like it was a good thing to do.

I did feel it was like a good thing to do. But I did find it a little bit tedious. And I would feel quite anxious
that mum might fall and she was anxious! And I would be very tired as well by this stage..." Daughter
(Severe stages – Community).

270 Conversely, it was suggested that carers also had positive experiences of keeping the person
271 with dementia active, such as bonding with the person living with dementia during the activity, having
272 quality time together, developing support networks with peers and improving their own health.

- 273 "I think that it is quite bonding because I think they are learning more about their family."
- 274 Activity coordinator (All stages Nursing home).
- In addition, carers could see their burden of care being alleviated by witnessing an improvedbehaviour from the person with dementia and ensuring their functional independence.
- 277 "I think we hadn't really thought ahead, to when mum would lose her mobility... what would
 278 we do then? Or how would we cope? So it seemed very important [to keep her mobile]" Daughter
 279 (Severe stages Community).
- 280 Maintaining independence was not only considered important for managing carer burden, but281 also key for people living with dementia:
- 282 "Well, you need exercise, don't you? Otherwise you just would just tighten up and wouldn't be
 283 able to do things, surely. Person living with dementia (Mild to moderate stages Care home)
- 284 When supported by others, activity was also an opportunity to give family carers a break.
- 285 "In respect to the fact that I know John is somewhere doing something he enjoys, that is
 286 independent of me, he is not reliant on me for that at all, I don't have a huge part in it, he has his own
 287 friends down there, he has something that is entirely his. And it is a form of activity. It gives me free
 288 time..." Wife (Mild to moderate stages Community).
- 289

290 Maintaining identity

This theme related to a continuity of identity that was achieved through activity, by enabling people living with dementia to do what they are passionate about. Activity was described by patients, carers and professionals, as a means by which the person with dementia could stay in control, keep life as "normal as possible" and minimize the disruption caused by the diagnosis of dementia.

295 "I suppose it is important... it sort of, as far as you can, just carry on! You know, it might not
296 be as normal but, just do what you can! As long as you can!" Person living with dementia (Mild to
297 moderate stages – Community).

298

299 Having a role towards others

300 Activity was also reported to be used as a source of social benefits; fighting loneliness and301 isolation.

302 "Because I imagine it can be a very lonely existence [to live with dementia], and if, if through
303 sport in general, or whatever, that can be improved, that can only be fantastic." Private company (All
304 stages – Community).

Activity generated benefits such as feeling included, gaining a sense of belonging to groups, teams and being active members of society. It also allowed people with dementia to maintain or assume new roles, giving meaning to a new stage of life. It offered people with dementia the opportunity of being interested in a cause and feeling valued, by gaining interest from others.

309 "That's why I came here [became a volunteer in a gardening centre]. Just to be able to help
310 them (...), because I know what it is like (...) and now I understand how the team gets together and do
311 it. You know what I mean? It is great!" Person living with dementia (Mild to moderate stages –
312 Community).

313

Being connected to the present

315 While the diagnosis of dementia was described by participants as taking the person away to a

difficult-to-access "dementia world", activity was described as an anchor to the present. It is a way of
retrieving positive memories and emotions to the present and "living in the moment". Whilst active,
people with dementia aimed to have a fulfilling time, filled with opportunities and new experiences.
"Being active" was seen as having a positive, proactive attitude of wanting to be alive and wanting to
fight the hopelessness of the diagnosis.

321 "So, so yeah if you've got, if you have just been diagnosed I would say: try not to be put off by
322 the bigger picture. (...) And try and still do things. (...) Do things that they are used to do. But differently.
323 So sort of fight the dementia if you like. Not fight against it, because you can't. Hopefully we will get a
324 cure one day, but actually still do things in spite of it if you like." Daughter (All stages – Community
325 and Care home).

326 *"Well, because it [gardening] gets me to stay out and being alive."* Person living with dementia
327 (Mild to moderate stages – home).

328

329 Delivering good quality care

For those providing formal or informal care, delivering activity that people living with dementia could adhere to was considered part of delivering "good care". It was considered "good" because it was cost-effective and specialised for dementia. Participants also reported that providing activity promotes a positive reputation for institutional settings.

"From the perspective of the retirement community, (...) I think they liked the fact that it
reflected well on them, that they were doing this, so they (...) had it permanently on their website and
things like that." Private company (All stages - Community and residential homes).

337 Providing activity also promoted staff satisfaction and retention. From the perspective of family
338 carers, the provision of physical activity helped them feel that they had chosen the right care for their
339 loved one.

For the carers [live-in carers, privately funded by relatives], you know, our job is to keep the
carers content. If we can keep them happy we can keep them. And changing a live-in carer is a challenge
as you can imagine. Son (Stage not known – Community).

343

344 **Discussion**

345 This qualitative study precedes the consensus phase of developing a Core Outcome Set to be used to evaluate physical activity interventions for people with dementia, and represents an innovative 346 347 methodological approach in Core Outcome Set development. To our knowledge this is also the first 348 qualitative study exploring outcomes of physical activity across dementia types and stages of disease progression, and first qualitative study being published as a pre-consensus phase of a Core Outcome 349 350 Set. A list of 77 outcome domains, including 10 novel outcome domains, was developed. Most outcome 351 domains were relevant across stakeholders, settings and stages of disease progression, and were organised under five themes: "Being well and staying well", "Maintaining identity", "Having a role 352 353 towards with others", "Being connected to the present" and "Delivering good quality care". This study 354 makes two distinct contributions to knowledge: it informs the development of Core Outcome Set methodology; provides new in-depth knowledge about the importance of physical activity in dementia 355 356 care.

357

358 Implications for Core Outcome Set methodology

A total of 10 outcome domains would have been missed in the consensus phase, had this qualitative study not been undertaken. This is a surprisingly high number of outcome domains, as it is often reported that qualitative studies do not add any outcomes to those already in the literature [27].

In line with other Core Outcome Sets for progressive conditions, it was anticipated that the consensus study would be subdivided according to the different stages of disease progression [28]. However, our findings indicate that outcomes of physical activity overlap greatly across settings and 365 stages of dementia. The initial protocol [28] was therefore changed to a single consensus survey. The 366 potential for qualitative findings to inform the structure and design of a Core Outcome Set had not been 367 previously identified [5], and it should be taken into account by future Core Outcome Set developers.

368

369 Contributions to knowledge about relevant effects of physical activity

370 The new outcomes "carer developing friends and getting support"; "meeting individual needs of patient and family"; "becoming interested and gaining interest from others"; "reframing and 371 372 revisiting the person with dementia" (Table 2a) indicate the important role that physical activity has in 373 supporting people living with dementia and their carers in both adapting to the diagnosis and as 374 dementia progresses. The use of physical activity to maintain the identity as that of "someone active" despite the diagnosis is explained in this study, supporting findings from previous qualitative work [14]. 375 However, the use of activity to embrace new roles (as shown, by the new outcome domains "reframing 376 377 the person with dementia" and "carer making friends and getting support") is a new perspective, 378 indicating that physical activity can be used as a tool, not only to maintain, but also to adapt a sense of self-identity, as dementia progresses. The concept of exercise identity was shown to be key in a recent 379 380 model of exercise participation for people with chronic conditions, highlighting how patients choose to 381 exercise according to their age and gender identity, social and cultural norms [29]. Physical activity can 382 therefore be used by people living with dementia, as in other chronic conditions, to continuously 383 (re)frame their identity, while living with a progressive condition.

The remaining new outcomes generated by this study reflect potential physical needs of people, either at later stages of dementia, or of those with multiple comorbidities: "improving posture", "preventing incontinence", "managing lower limb oedema" and "managing pressure ulcers". The fact that these are new outcomes, demonstrates the lack of research into physical activity for people with severe dementia [3] and provides new insights into the potential that physical activity may have across stages of disease and for addressing the multi-morbidity that often accompanies the progression of dementia [30]. The present study highlights how physical activity interventions can support families living with dementia from early diagnosis and throughout their dementia journeys; a key message in dementia care guidelines and policies [31].

394

395 Strengths and Limitations

396 In-depth interviews were a challenging method for patients at later stages of dementia or those with 397 limited verbal communication, leading to a sample with more carers than people living with dementia, 398 and a relatively small sample of people living with dementia. This is a potential limitation because this 399 Core Outcome Set aims to be applicable to physical activity interventions including people with 400 dementia in all stages of the condition, and with no restrictions in terms of communication abilities. 401 Including a higher proportion of carers was a successful strategy to gather the views of those closest to people living with late stage dementia. The present study also informs the next stage of the development 402 403 of this Core Outcome Set (a consensus study), where a larger sample of people living with dementia 404 will be recruited.

The identification of outcomes from the interviews was conducted by one researcher only. To minimise this potential limitation, the analysis benefited from patient and public involvement through regular reflections with a former carer of someone living with dementia as the data analysis progressed; the final analysis findings were also 'member checked' by four participants [25]. The process of merging the list of outcomes from this qualitative study with the outcomes in the literature was conducted independently by two researchers, increasing the rigor of this stage of data analysis.

411

412 **Conclusion**

This qualitative study makes an important contribution to Core Outcome Set methodology. By adding 10 outcome domains to the list previously generated from published literature it has demonstrated the important role qualitative methods can play in ensuring outcomes meaningful to 416 patients, carers and professionals are not missed. This study also highlights the value of physical activity 417 across the stages of dementia progression. Whilst confirming findings from previous studies that 418 physical activity can contribute to "Being well and staying well" and "Delivering good quality care" it 419 has also identified an important new finding that physical activity is important in the process of adapting 420 to the diagnosis through "Maintaining identity", "Having a role towards and with others" and "Being 421 connected to the present".

422

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429

430 **Conflicts of interest**

431 None to declare.

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Table 1- Sample characterisation.

Stakeholder group 1: people with dementia and their carers (n=19)	Mean (SD) or n (%) People living with dementia	Mean (SD) or n (% Carers
Role		
People living with dementia	5 (26%)	-
Spouses	-	6 (32%)
Adult children or children in law	-	8 (42%)
Demographics		· · ·
Age (years)	75 (11.8)	62 (12.4)
Gender (female)	3 (60%)	10 (71%)
Levels of physical activity	58.5 (74.0)	-
Mini Mental State Examination	19.2 (3.9)	-
Index of Multiple Deprivation	7.8 (1.9)	6 (2.7)
Experience of doing or supporting activity in which of the following		
setting(s)		
Community	3 (60%)	9 (64%)
Care or nursing home	2 (40%)	2 (14%)
Assisted living	0 (0%)	4 (29%)
Hospital	0 (0%)	2 (14%)
Living with the following stage of disease progression or having		- (11/0)
experience of supporting activity for a relative through the following		
stage(s) of disease progression		
Mild to moderate	4 (80%)	6 (43%)
Moderate to severe	1 (20%)	0 (0%)
All stages	1 (2070)	7 (50%)
Not known	-	1 (7%)
Type of dementia	-	1 (7%)
	2(400/)	0(640/)
Alzheimer's disease	2 (40%)	9 (64%)
Mixed dementia	1 (20%)	1 (7%)
Vascular dementia	1 (20%)	1 (7%)
Lewy body dementia	0(0%)	2 (14%)
Young onset Alzheimer's disease	1 (20%)	0 (0%)
Not Known	0 (0%)	1 (7%)
Stakeholder group 2: professionals (n=10)	Mean (Sl	D) or n (%)
Role		
Physiotherapists	,	40%)
Occupational Therapists	,	20%)
Activity coordinators	,	10%)
Charities		20%)
Private companies		10%)
Involved in delivering research	1 (10%)
Demographics		
Age (years)		(10.1)
Gender (female)	5 (50%)
Professional setting		
Community	7 (70%)
Care or nursing home	7 (70%)
Hospital		40%)
Experience per stage of disease progression	· · · · · · · · · · · · · · · · · · ·	
Experience in care for people with mild to moderate dementia	1 (10%)
Experience in care for people at all stages of dementia		90%)

519 Table 2a. Outcome domains identified in this qualitative study (n=10), but not previously identified in the literature.

NEW Outcome domains identified in this qualitative study (n=10), and not previously identified in the literature

Outcome domain	Scope	Stakeholder		Stage			Setting		
identified:		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
Positive outcome do	mains (n=8):								
Improving posture	Includes sitting and standing posture.	х	х	X	х	х	Х	-	х
Managing lower limb oedema	Fluid retention in the lower limbs.	-	Х	-	-	Х	х	-	х
Managing pressure ulcers	Preventing pressure ulcers and recovering skin integrity.	Х	Х	Х	х	Х	Х	-	х
Preventing incontinence	Regularly using the toilet, by mobilising to the toilet or commode instead of using a pad.	-	X	-	-	X	Х	-	х
Carer developing friendships and peer support	Family carers meeting other relatives of people living with dementia and developing a network of friendship and peer support.	x	x	х	х	x	X	-	х
Meeting individual needs of patient and family	Meeting individual needs of the person living with dementia. These includes identity, physical, spiritual, emotional and social needs. Meeting tailored needs of families.	x	x	х	х	х	X	x	Х
Becoming interested and gaining interest of others	Gaining the interest of the person living with dementia and the interest of staff, formal carers and relatives. Getting relatives and formal carers to know the person with dementia and becoming interested in what they can do.	Х	х	x	x	X	Х	X	X
Reframing and revisiting the person with dementia	Recovering one's "old self" even if for brief moments. Relatives having moments of seeing the "old" person with dementia by seeing them active as they were before the diagnosis. Relatives and staff or formal carers being surprised by the ability of the person living with dementia. Using activity to highlight what the person with dementia can still do.	X	X	х	x	x	X	х	-
Negative outcome do	omains or risks of physical activity (n=2):								
	Eating or drinking something that should not be ingested, by confusing it with real food or drink.	X	X	X	Х	X	Х	-	-

520	something harmfulNot being able to sleep after an activityThis was linked to possible changes of environment or routine - x - x x - x - x - x - x - x - x - x
521 522	"prof. and researchers" - professionals and researchers; "patients and carers" – people living with dementia and their informal carers or relatives. Boxes identified with "x" indicate that the outcome domain has been identified in that context. Boxes identified with "-" indicate that an outcome domain has <u>not</u> been identified in that particular context.
523	
524	

525 Table 2b - Outcome domains measured and referred to in the literature, but not identified in this qualitative study (n=9)

Outcome domains measured or referred to in the literature, but NOT identified in this qualitative study (n=9)

	Scope	Stakeholder		Stage			Setting	Setting			
identified:		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital		
Positive outcome do	mains (n=4)										
Carer mobility	Carer mobility and balance, ability to walk with less joint pain.	х	Х	х	х	х	Х	-	-		
Carer mood	Simply described as "carer mood".	х	-	-	х	-	Х	-	-		
Carer quality of life	Carer wellbeing and quality of life. At times linked to carer burden.	Х	-	X	х	X	х	-	X		
Carer sleep	Improved carer sleep quality.	х	-	-	х	-	х	-	-		

Being admitted to hospital or experiencing a deterioration in health	• Being hospitalized or admitted to an emergency department. Experiencing a deterioration of overall health or becoming too unwell to continue activity.	X	-	х	х	Х	X	X	-
Discovering cysts	Ganglion cyst.	х	-	Х	-	-	х	-	-
Feeling dizzy, nauseous or fainting	Feeling dizzy, nauseous or light-headed. Having a syncopal episode.	X	-	х	Х	x	х	-	-
Increasing mortality	Number of deaths during activity or within the time period while the person with dementia was a participant in an activity intervention.	X	-	х	Х	x	х	х	-
Moving into care	Being placed into an institution for permanent full-time care.	х	-	х	х	х	Х	-	-

527 "prof. and researchers" - professionals and researchers; "patients and carers" – people living with dementia and their informal carers or relatives. Boxes identified with "-" indicate that an

outcome domain has <u>not</u> been identified in that particular context.

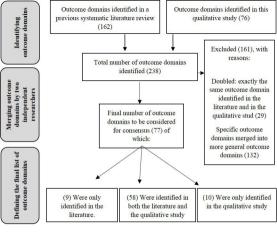


Figure 1- Flowchart of the development of final list of outcome domains to be considered in the next phase: consensus study.

Outcomes of Physical Activity for People Living with Dementia: Qualitative Study to Inform a Core Outcome Set.

Supplementary Material – Outcome domains (n=77) with the scope and context in which each outcome domain has been identified. Outcome domains identified in this qualitative study, but not previously identified in the literature are highlighted in grey (10).

Outcome domain	Scope	Stakeholder		Stage			Setting		
identified:		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
THEME: being well an	nd staying well								
Achieving or maintaining functional abilities and independence	Maximizing abilities using multiple body movements, being able to complete transfers, avoiding being bedridden, being independent in basic and instrumental activities of daily living, including handling cutlery and maintaining coordination to feed oneself. Feeling independent.	X	X	х	x	X	x	x	X
Attenuating disease progression	Maintaining abilities for as long as possible. Preventing decline and delaying onset of health complications. Includes physical and cognitive decline as well as perceived/expected decline in wellbeing	х	x	Х	Х	Х	х	х	х
Avoiding being admitted to hospital or being discharged quicker	Avoiding hospital admissions and reducing length of stay following a hospital admission, reducing social and health care use.	x	x	х	x	х	x	х	x
Being more sociable and talkative	Initiating and keeping conversations, sharing stories and having something to talk about.	Х	X	Х	x	x	х	Х	Х
Enjoying activity and getting a sense of success and pleasure out of it	Having a sense of satisfaction, achievement, completion, success and reward or getting pleasure and joy as a result of activity. Finding activity appealing and feeling good about doing it.	х	Х	x	х	х	x	х	х
Feeling more relaxed, settled and peaceful	Feeling calmer. Getting a sense of peace and relaxation. Being released from anxiety or confusion and feeling better in oneself post activity. Absence of physical and mental stress.	X	х	х	х	х	x	х	Х
Having a healthy routine and a balanced life	Having a sense of order in the day, Keeping the momentum, getting the recommended hours of sleep and having good sleep hygiene and sleep patter. Having a healthy number of meals per day. Having a balance of	х	х	Х	Х	Х	х	х	Х

Outcome domain	Scope	Stakeholder		Stage			Setting		
identified:		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
	leisure, rest and activities of daily living. Having structure to the day. Knowing and keeping one's own routine.								
Improving ability to complete movements and tasks without difficulty	Incorporates fine motor skills, dexterity, hand-eye coordination, praxis and use of quick-reactions. The literature also refers to reaction time, agility, motor skills and ability to conduct movements rightly.	x	х	х	х	х	x	х	-
Improving cardiorespiratory and cardiovascular health	Maintaining a healthy weight, maintaining or improving endurance, circulation and lung function. The literature also included the following components: heart rate, blood pressure, maximum oxygen consumption, breath holding duration, oxygen saturation, respiratory exchange rate, respiratory rate and vital capacity.	X	X	х	х	x	x	X	Х
Improving depressive symptoms and preventing depression	Feeling less depressed. Impacting on how the person sees her/himself; wanting to get out of bed in the morning and gaining motivation to do things.	x	x	Х	х	х	х	X	х
Improving dietary intake	Being hungry or having good appetite; eating and drinking more than usual; eating well; eating normally as opposed to not eating enough.	Х	Х	Х	Х	х	x	Х	-
Improving mood and affective function	Mood levels; lifting mood or being in better mood; being content, brighter, happier or having fun. Having a positive attitude. Showing less negative emotions.	x	x	Х	х	х	х	X	х
Improving or maintaining balance	Balancing oneself while moving and shifting weight. Challenging balance. Linked to falls risk.	Х	Х	х	х	x	х	Х	х
Improving or maintaining mobility	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.	X	X	x	X	х	x	х	X
Improving or maintaining structure and function of the brain	Improving, cognition, concentration, alertness, attention, memory and reducing confusion. Seeing changes in brain volumes and physiology of the brain. Being able to calculate, read and recognize places. Keeping the brain active. The literature includes additional specific aspects of cognition, such as: executive function, processing speed, different types of memory, Perception and visual-spatial awareness, body awareness, agnosia, reasoning and ability to follow instructions. Fluid biomarkers are also included in the literature.	Х	Х	Х	Х	x	X	X	х
Improving posture	Includes sitting and standing posture.	х	х	х	х	х	х	-	х

Outcome domain	Scope	Stakeholder		Stage			Setting		
identified:		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
Improving quality of life and wellbeing	Health related quality of life, in opposition to living longer with poor quality. Also referred to as "raising standards of living". Includes physical, mental, emotional and social wellbeing. Generally feeling better, comfortable (physically and emotionally), improving stamina and managing fatigue. Feeling joy and satisfaction about being alive.	X	X	X	X	X	X	X	X
Increasing levels of physical activity	Amount of physical activity performed by the person with dementia within a defined period of time. Includes measures of time, distance, repetitions and intensity (e.g. weights). The literature also includes the levels of restricted activity (e.g. number of days with no activity).	x	x	х	x	Х	x	х	x
Keeping healthy, fit and active	Overall health, general ability or performance. Being fit, strong and ready for activity. Staying well and having less medical diagnosis.	Х	Х	х	х	Х	х	X	Х
Living longer	Reducing mortality, preventing deaths, lasting longer.	х	х	х	х	х	х	Х	-
Maintaining current care arrangements	Living at home for as long as possible and avoid institutionalization. Avoiding increasing need for higher level of care within the same setting.	X	x	Х	Х	X	X	x	Х
Maintaining functional range of movement	Maintaining joint health and flexibility from upper and lower limbs. Avoiding contractures and maintaining movement quality. Maintaining or increasing amplitude of movement. Includes achieving the necessary range of movement to complete functional talks (e.g. putting a coat on).	x	X	х	x	Х	x	X	x
Managing behaviours	Overcoming challenging behaviours or behavioural issues, including agitation and aggression, apathy, passivity or lack of eye contact, distress, shouting behaviours, restlessness, pacing, wandering, and feeling angry and frustrated. Using inappropriate language or handling objects inappropriately and "sun downing". Reducing need for restraint.	X	Х	X	X	X	x	X	х
Managing lower limb oedema	Fluid retention in the lower limbs.	-	Х	-	-	Х	х	-	х
Managing pain	Lower limb pain; arthritic and muscular pain; pain due to constipation.	Х	х	х	х	х	х	-	х
Managing pressure ulcers	Preventing pressure ulcers and recovering skin integrity.	X	X	X	X	Х	X	-	Х
Opening bowels	Regular bowel movements. Linked to a reduction in the use of laxative medication.	Х	Х	Х	Х	Х	-	Х	Х
Preventing boredom	Relieving and preventing boredom by changing scenery, experiencing sensory or cognitive stimulation. Avoiding excessive sleep due to lack of interest or stimulation.	X	х	Х	Х	х	X	X	Х

Outcome domain	Scope	Stakeholder		Stage			Setting		
identified:		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospita
Preventing falls	Number of fallers, overall number of falls, number of falls sustained by one person with dementia. Link to health care costs associated with managing fall related injuries (e.g. fractures). The literature also includes concepts of falls risk and fear of falling.	X	X	X	X	х	X	X	Х
Preventing incontinence	Regularly using the toilet, by mobilizing to the toilet or commode instead of using a pad.	-	Х	-	-	x	X	-	Х
Reducing anxiety	Distracting from a state of anxiety and reducing levels of anxiety.	Х	Х	Х	х	х	Х	-	-
Reducing use of medication	Taking a reduced number of different drugs and and/or the overall amount of medication. This includes medication for physical and mental health purposes and was linked to a reduction in health related costs.	x	X	X	Х	х	x	x	Х
Subtheme: Impacting th	ne lives of carers								
Carer developing friendships and peer support	Family carers meeting other relatives of people living with dementia and developing a network of friendship and peer support.	x	X	х	X	х	x	-	X
<u>Carer mobility</u>	Carer mobility and balance, ability to walk with less joint pain.	Х	Х	Х	х	х	Х	-	-
Carer mood	Simply described as "carer mood".	Х	-	-	Х	-	Х	-	-
Carer quality of life	Carer wellbeing and quality of life. At times linked to carer burden.	Х	-	Х	Х	х	Х	-	х
Carer regaining sense of satisfaction and achievement	Carers feeling positive about the person with dementia being active, improving and having a fulfilling time. In the literature this was linked to confidence in their care abilities and carers' satisfaction with the intervention.	x	Х	х	х	х	X	х	X
Carer sleep	Improved carer sleep quality.	х	-	-	х	-	Х	-	-
Decreasing carer burden or distress	Activity may reduce the burden of care in the long term by maintaining functional independence of the person with dementia, accessing support from professionals and experiencing less challenging behaviour; In the short term by giving the carer a break while the person with dementia is involved in activity and needing less input from the carer.	X	x	x	X	X	x	X	X
Improving carer general health	Includes weight management, and overall wellbeing and health. In the literature this was measured as the carer's use of health and social care services and therefore linked to costs.	x	Х	х	X	х	x	-	-
Increasing carer levels of physical activity	Joining in with the person with dementia, adding to their habitual levels of activity.	х	х	Х	Х	Х	х	Х	х

Outcome domain	Scope	Stakeholder		Stage			Setting		
identified:		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
Negative outcome: Increasing carer burden or distress	Carers may face an increase in workload: being/feeling responsible to offer activity and sometimes persuade them to join in activities. For carers, activity can imply effort, fatigue and negative emotions of guilt, frustration and worry about the patient safety. It may increase risks of negative health outcomes to the carer.	X	x	X	X	Х	x	X	х
Reducing carer depression	Lack of activity and engagement for the person with dementia was linked to carer depression.	Х	x	X	X	-	X	-	-
Subtheme: negative effe	ects or risks of physical activity								
Becoming aggressive, agitated, more confused, anxious, depressed or distressed during activity	Becoming challenging, frustrated, rude or overstimulated during the activity. In some cases, activities with these effects were considered not appropriate for the person with dementia and are often interrupted. Refusing to go back into a care setting after an activity in a different environment.	х	х	X	X	x	X	X	x
Becoming short of breath during activity	Shortness of breath, or needing to "catch one's breath" and interrupting the activity because of it.	Х	х	х	-	-	Х	X	-
<u>Being admitted to</u> <u>hospital or</u> <u>experiencing a</u> <u>deterioration in health</u>	Being hospitalized or admitted to an emergency department. Experiencing a deterioration of overall health or becoming too unwell to continue activity.	Х	-	х	х	X	x	х	-
Being in pain or experiencing discomfort during or after the activity	Includes muscle soreness or stiffness after exercising. Complaining of pain or experiencing physical discomfort during activity. Not being able to be as active as usual in the day(s) after the activity.	Х	x	x	x	Х	X	x	х
Discovering cysts	Ganglion cyst.	х	-	Х	-	-	Х	-	-
Eating or drinking something harmful	Eating or drinking something that should not be ingested, by confusing it with real food or drink.	Х	х	Х	Х	х	Х	-	-
<u>Feeling dizzy,</u> nauseous or fainting	Feeling dizzy, nauseous or light-headed. Having a syncopal episode.	X	-	X	X	X	X	-	-
Feeling tired or exhausted	Feeling tired, drained, exhausted. Described as something that would stop the activity and that should be used to monitor the intensity of the activity.	x	х	х	х	x	x	X	х
Getting lost	Not being able to find the way back after an activity. Having to use technology to find the person with dementia.	Х	х	Х	Х	x	Х	Х	-

Outcome domain identified:	Scope	Stakeholder		Stage			Setting		
		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
Having a negative experience	Triggering negative emotions or feelings (e.g. embarrassment or unhappiness). Having an unsatisfying experience. Activity reinforcing illness and loss of roles (e.g. Letting the team down) and therefore having a negative impact on perceptions of wellbeing.	X	X	x	X	х	X	Х	х
Increasing cardiovascular risk	Suffering a Transient Ischemic Attack or developing cardiac pathology. This was also a reason for caution when involving a person with dementia in activity.	х	-	Х	Х	x	X	-	Х
Increasing falls, falls risk, fall related injuries, near falls and fear of falling	Sustaining falls or increasing falls risk by being active. Sustaining injuries after a fall (e.g. fractures) and having to attend emergency care because of falls. Being about to fall, but being able to save oneself. Increasing fear of falling and reducing confidence in walking due to fear of a fall.	X	X	x	x	X	x	x	Х
Increasing mortality	Number of deaths during activity or within the time period while the person with dementia was a participant in an activity intervention.	X	-	х	х	х	х	X	-
Moving into care	Being placed into an institution for permanent full-time care.	Х	-	х	Х	х	Х	-	-
Not being able to sleep after an activity	This was linked to possible changes of environment or routine caused by the activity (e.g. coming back to care after having been on holiday).	-	Х	-	x	x	-	Х	-
Sustaining injuries (not fall related) or hurting others during activity.	Includes injuries to muscles and joints. May result from doing the wrong exercise or overdoing it; or from "bumping into" objects or fellow participants.	X	-	х	x	Х	x	X	Х
THEME: Maintaining i	dentity								
Feeling free and in control of one's life	Doing something independent from the carer, having rights, choices and interests and doing what one wants to do. Being in control of one's own life and feeling free to ask for activity.	х	х	X	х	х	X	x	х
Improving self- esteem, self-worth and self-respect	Sense of self, feeling good about (still) being active and strong and (still) being good at a certain activity. Feeling listened to, valued and respected.	х	x	Х	Х	x	Х	X	x
Making the best of ones' physical abilities	Using one's physical being. Using all available skills and abilities. Expressing a physical self. Seeking movement as a routine part of life.	X	X	х	X	x	х	Х	х
Meeting individual needs of patient and family	Meeting individual needs of the person living with dementia. These includes identity, physical, spiritual, emotional and social needs. Meeting tailored needs of families.	х	x	Х	X	X	Х	X	X

Outcome domain	Scope	Stakeholder		Stage			Setting		
identified:		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
Seeing the person before the disease	Being able to connect with the person rather than focusing on the disease through activity. Activity as a constant reminder that the person with dementia is a person and not a diagnosis.	Х	х	X	X	X	х	X	X
Wanting life to be as normal as possible and continue doing what they have always done.	Feeling normal by keeping moving and keeping activities that are part of a routine, define identity and outline what "normal life" looks like for an individual. Keeping going despite the diagnosis.	X	X	x	х	X	х	x	x
FHEME: Having a role	towards others								
Becoming interested and gaining interest of others	Gaining the interest of the person living with dementia and the interest of staff, formal carers and relatives. Getting relatives and formal carers to know the person with dementia and becoming interested in what they can do.	x	x	x	X	х	X	х	x
Experiencing relationships	Doing activities together with staff or relatives and rebuilding relationships. Seeking interaction with others; fighting isolation and loneliness.	х	x	Х	х	Х	х	X	х
Getting involved, engaged, joining in and feeling included	Taking part and being part of an activity. Being involved and included.	х	x	Х	Х	х	x	X	х
Having a role, a purpose towards others and sense of belonging	Feeling useful. Being part of a family, team or a group. Being a volunteer. Helping family, neighbours and peers. Being occupied with meaningful activity. Doing what one is passionate about and having something to look forward to.	x	x	X	X	х	X	x	x
THEME: Being connect	ted to the present								
Bringing back memories and emotions – reminiscence	Tapping into past experiences. Doing activity that relates to and can be recognized by the person with dementia. Triggering memories.	x	x	x	X	х	X	x	x
Communicating and expressing oneself through movement	Using movement as means of communicating information and emotions. Moving spontaneously and naturally. The literature includes the using facial expressions, and improving language ability and verbal fluency.	x	x	х	X	х	x	х	x
Having increased life opportunities	Getting out of the house, accessing daylight and the outdoors and accessing public spaces and services (including rehabilitation). Being	х	х	Х	х	Х	Х	Х	Х

Outcome domain identified:	Scope	Stakeholder		Stage			Setting		
		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
	allowed and having opportunity to experience activity. Not being forgotten about.								
Living in the moment	Being anchored to the present by activity. Learning or doing something new. Having an adventure. Not having to think about anything else.	Х	X	X	X	Х	X	Х	X
Living a fulfilled life rather than just existing	Dementia is not the end. Not be willing to "just sit around waiting to die". Being lively, or coming back to life when active. Staying engaged with life, enjoying every small aspect of life and having a fulfilling time while having dementia.	x	x	х	x	X	X	X	x
Reframing and revisiting the person with dementia	Recovering one's "old self" even if for brief moments. Relatives having moments of seeing the "old" person with dementia by seeing them active as they were before the diagnosis. Relatives and staff or formal carers being surprised by the ability of the person living with dementia. Using activity to highlight what the person with dementia can still do.	x	X	х	х	х	Х	х	-
THEME: Delivering go	ood quality care								
Adhering to activity	The extent to which an activity is completed according to a pre-set criteria of duration, frequency and intensity.	Х	х	x	x	X	х	X	x
Improving care delivery	For families, good care meant care that offers opportunities for activities that reflect the needs of the person with dementia. For organizations, offering activity for people with dementia meant staff retention and staff satisfaction. An association is made between providing activity and offering good quality of care, that is cost effective in relation to health and social care for patients and carers. It includes defining the longevity of any positive effects of activity.	x	Х	x	X	x	х	х	x

"prof. and researchers" - professionals and researchers; "patients and carers" – people living with dementia and their informal carers or relatives. *Boxes identified with "x" indicate that the outcome domain has been identified in that context. Boxes identified with "-" indicate that an outcome domain has not been identified in that particular context.* New outcome domains generated by this qualitative study are *highlighted; outcomes measured or referred to in previous literature, but not mentioned in this qualitative study are underlined.*