

1 **Outcomes of Physical Activity for People Living with Dementia:**

2 **Qualitative Study to Inform a Core Outcome Set**

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41 **Abstract**

42 **Background:** The need for a Core Outcome Set to evaluate physical activity interventions for people
43 living with dementia, across stages of disease and intervention settings has been established. This
44 qualitative study precedes the consensus phase of developing this Core Outcome Set and aims to: (i)
45 compare the outcomes identified by patients, carers and professionals to those previously reported in
46 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.

51 **Results:** A comprehensive, inductively derived list of 77 outcomes, common across stages of dementia
52 and intervention setting, was put together for the consensus phase of this Core Outcome Set: ten of these
53 were new outcomes generated by this qualitative study. Five themes explained why stakeholders
54 perceived physical activity outcomes as important for people living with dementia: “being well and
55 staying well”, “having a role towards others”, “maintaining identity”, “being connected to the present”
56 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.

60

61 **Contribution of the paper:**

- 62 • Qualitative methods ensure relevant outcomes are not missed in Core Outcome Sets.
- 63 • Physical activity can enable a constant adaptation of self-identity to patients and carers as the
64 dementia progresses and may bring positive outcomes to those living with severe dementia
65 and/or comorbidities.
- 66 • Physical activity for people living with dementia is linked to good quality care, overall wellness,
67 living in the present and being connected with others.

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

70

71 **Introduction**

72 Dementia is a major cause of dependency and disability among older people, resulting in
73 increased burden on individuals, carers and health care services [1]. The need for research into
74 interventions to improve care of people living with dementia is evident [2]. Physical activity, defined
75 by the World Health Organization as “any bodily movement produced by skeletal muscles that requires
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
78 literature review [3] identified substantial heterogeneity of outcomes reported in physical activity
79 research for people living with dementia. This is one factor limiting meta-analyses and the
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].

87 A gold standard for Core Outcome Set development is yet to be defined. The inclusion of
88 qualitative methods preceding the consensus phase of COS development, represents a methodological
89 innovation considered particularly necessary when research in the field of the Core Outcome Set lacks
90 sufficient qualitative work [5]. Most qualitative studies about physical activity for people with dementia
91 are linked to a specific intervention and are aimed at exploring feasibility, barriers and facilitators to
92 that intervention [6-10]. The few available qualitative papers, not linked to a specific intervention,
93 include only care home settings [11, 12] or people living with early stages of dementia [13, 14] and do

94 not meet the needs of a Core Outcome Set applicable across intervention settings, types of dementia
95 and stages of the condition. Furthermore, these qualitative studies are not centred on intervention
96 outcomes, and therefore many outcomes, relevant to participants, may have been missed during data
97 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.

106

107 **Design and Methods**

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

110 **Registration and Ethical Approval**

111 This study is part of the development of a Core Outcome Set, registered with the Core Outcome
112 Measures in Effectiveness Trials initiative¹. Ethical approval was obtained from the ethics committee
113 at the Faculty Health Sciences, University of Southampton (ethics number: 19524). All participants
114 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
117 and events. Posters were made available in public spaces (e.g. libraries, churches, social centres) and
118 flyers distributed via gatekeepers in charities and support groups. The study poster and a short
119 description of this research was made available through websites and newsletters of professional
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
122 (verbally and in a writing via the participant information sheet). A date for interview was only arranged
123 with those who wanted to participate. A phone call was made the day before the interview to offer any
124 further clarifications and confirm the interview date. Formal consent was recorded on the day of the
125 interview.

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

131

132 **Inclusion criteria**

133 The following participants were included:

- 134 • People with a diagnosis of dementia, with capacity to consent to take part in research
135 at the time of data collection and able to communicate verbally in English;
- 136 • Family members who were currently involved or had previously been involved in the
137 care of a relative living with dementia;
- 138 • Professionals who have been involved in promoting, designing or supporting physical
139 activity for people with dementia.

140

141 **Exclusion criteria**

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

147

148 **Sampling**

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

- 151 • Stage of disease progression, determined by the Mini-Mental State Examination score,
152 completed by the first author (ACG - interviewer) immediately prior to the interview: “Mild to
153 moderate” – 17 to 26; “Moderate to severe” - 10 to 16 and “Severe” – less than 10 [18];
- 154 • Type of dementia;
- 155 • Activity setting (i.e. community, care or nursing homes, assisted living; hospital);
- 156 • Levels of physical activity, determined by the score on the Physical Activity Scale for the
157 Elderly [19], completed immediately before the interview, with input from the carer; Scores range from
158 zero (no physical activity completed in the previous seven days) to 693.9 (maximum physical activity
159 level score);
- 160 • Socioeconomic deprivation, determined by the Index of Multiple Deprivation [20], using the
161 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 data
163 being collected made little or no difference to the codes being generated from the data analysis [21].

164

165 **Data collection**

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

171 The interview topic guide was designed to enable participants to discuss outcomes of physical
172 activity and explore the importance of such outcomes. Professionals and carers were interviewed face-
173 to-face or remotely (via telephone or video call), according to their preference. People living with
174 dementia were interviewed face-to-face, in a private venue of their choice, and encouraged to have a
175 relative or friend with them at all times. During the interviews with people living with dementia, the
176 following strategies were used, based on previous research [22], and the interviewer's [ACG]
177 experience of communicating with people with living with dementia: asking simple questions, giving
178 time for the person to answer, rephrasing the question with help from the carer, maintaining good eye
179 contact, reading body language for signs of fatigue or distress, offering breaks and choosing the time
180 and venue for the interview according to the person's needs. These strategies also facilitated the capacity
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**

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

190 **Aim 1:** Interviews were transcribed verbatim and analysed thematically [24]. The transcripts
191 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
193 outcomes of physical activity. An outcome was defined as "a perceived consequence or impact, positive
194 or negative, for people living with dementia, their carers or health services, whether intended or
195 incidental, arising from undertaking physical activity". Codes with equivalent semantic meanings were
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
198 researcher independent from this research team], against the outcome domains previously reported in
199 the literature [3]. A merged final list of outcome domains was created and the scope of each outcome
200 domain defined.

201 **Aim 2:** Outcome domains were thematically organised, by identifying patterns and connections
202 between outcomes that could be described by a higher level theme [24]. Each theme represented a
203 meaningful concept to answer the question: "why is physical activity important to people living with
204 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
209 10 professionals). The average interview duration was 67 minutes, ranging from 35 to 101 minutes.
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
212 was not possible to gather the views of the person living with dementia, the carer was interviewed
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.

216

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
219 the process of defining this list of outcome domains. Of the final 77 outcome domains, 10 (8
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
223 group, stage of disease progression and activity setting. An extended version of these tables including
224 all 77 outcome domains, which will be considered in the consensus phase, can be found in
225 supplementary material.

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

230

231

232 **Aim 2: Understanding why physical activity is important**

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

237

238 **Being well and staying well**

239 Participants across all stakeholder groups reported using physical activity to improve or
240 maintain multiple aspects of health and wellbeing of the person living with dementia, keeping an overall
241 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).

248 The data demonstrated that potential positive health benefits of physical activity for people
249 living with dementia are often influenced by other factors: participants weighed up the benefits against
250 the burden that physical activity may generate for people living with dementia; and the extent to which
251 supporting physical activity was beneficial or detrimental to carers. All stakeholder groups also
252 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)

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

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

262 Carers also reported on the burden of supporting activity: increased workload from keeping the
263 person living with dementia active, while managing their own health; and perceived negative emotions
264 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.*

267 *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*
268 *that mum might fall and she was anxious! And I would be very tired as well by this stage...*” Daughter
269 (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).

275 In addition, carers could see their burden of care being alleviated by witnessing an improved
276 behaviour 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, but
281 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**

291 This theme related to a continuity of identity that was achieved through activity, by enabling
292 people living with dementia to do what they are passionate about. Activity was described by patients,
293 carers and professionals, as a means by which the person with dementia could stay in control, keep life
294 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 and
301 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).

305 Activity generated benefits such as feeling included, gaining a sense of belonging to groups,
306 teams and being active members of society. It also allowed people with dementia to maintain or assume
307 new roles, giving meaning to a new stage of life. It offered people with dementia the opportunity of
308 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

314 **Being connected to the present**

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

316 difficult-to-access “dementia world”, activity was described as an anchor to the present. It is a way of
317 retrieving positive memories and emotions to the present and “living in the moment”. Whilst active,
318 people with dementia aimed to have a fulfilling time, filled with opportunities and new experiences.
319 “Being active” was seen as having a positive, proactive attitude of wanting to be alive and wanting to
320 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**

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

334 *“From the perspective of the retirement community, (...) I think they liked the fact that it*
335 *reflected well on them, that they were doing this, so they (...) had it permanently on their website and*
336 *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.

340 *For the carers [live-in carers, privately funded by relatives], you know, our job is to keep the*
341 *carers content. If we can keep them happy we can keep them. And changing a live-in carer is a challenge*
342 *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
346 used to evaluate physical activity interventions for people with dementia, and represents an innovative
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
349 progression, and first qualitative study being published as a pre-consensus phase of a Core Outcome
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
352 organised under five themes: “Being well and staying well”, “Maintaining identity”, “Having a role
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
355 methodology; provides new in-depth knowledge about the importance of physical activity in dementia
356 care.

357

358 **Implications for Core Outcome Set methodology**

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

362 In line with other Core Outcome Sets for progressive conditions, it was anticipated that the
363 consensus study would be subdivided according to the different stages of disease progression [28].
364 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
371 of patient and family”; “becoming interested and gaining interest from others”; “reframing and
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”
375 despite the diagnosis is explained in this study, supporting findings from previous qualitative work [14].
376 However, the use of activity to embrace new roles (as shown, by the new outcome domains “reframing
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
379 self-identity, as dementia progresses. The concept of exercise identity was shown to be key in a recent
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.

384 The remaining new outcomes generated by this study reflect potential physical needs of people,
385 either at later stages of dementia, or of those with multiple comorbidities: “improving posture”,
386 “preventing incontinence”, “managing lower limb oedema” and “managing pressure ulcers”. The fact
387 that these are new outcomes, demonstrates the lack of research into physical activity for people with
388 severe dementia [3] and provides new insights into the potential that physical activity may have across
389 stages of disease and for addressing the multi-morbidity that often accompanies the progression of
390 dementia [30].

391 The present study highlights how physical activity interventions can support families living
392 with dementia from early diagnosis and throughout their dementia journeys; a key message in dementia
393 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
402 people living with late stage dementia. The present study also informs the next stage of the development
403 of this Core Outcome Set (a consensus study), where a larger sample of people living with dementia
404 will be recruited.

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

411

412 **Conclusion**

413 This qualitative study makes an important contribution to Core Outcome Set methodology.
414 By adding 10 outcome domains to the list previously generated from published literature it has
415 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.

432

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516

517 **Table 1-** Sample characterisation.

Stakeholder group 1: people with dementia and their carers (n=19)	Mean (SD) or n (%)	Mean (SD) or n (%)
	People living with dementia	Carers
<i>Role</i>		
People living with dementia	5 (26%)	-
Spouses	-	6 (32%)
Adult children or children in law	-	8 (42%)
<i>Demographics</i>		
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)
<i>Experience of doing or supporting activity in which of the following setting(s)</i>		
Community	3 (60%)	9 (64%)
Care or nursing home	2 (40%)	2 (14%)
Assisted living	0 (0%)	4 (29%)
Hospital	0 (0%)	2 (14%)
<i>Living with the following stage of disease progression or having experience of supporting activity for a relative through the following stage(s) of disease progression</i>		
Mild to moderate	4 (80%)	6 (43%)
Moderate to severe	1 (20%)	0 (0%)
All stages	-	7 (50%)
Not known	-	1 (7%)
<i>Type of dementia</i>		
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 (SD) or n (%)
<i>Role</i>		
Physiotherapists		4 (40%)
Occupational Therapists		2 (20%)
Activity coordinators		1 (10%)
Charities		2 (20%)
Private companies		1 (10%)
Involved in delivering research		1 (10%)
<i>Demographics</i>		
Age (years)		43 (10.1)
Gender (female)		5 (50%)
<i>Professional setting</i>		
Community		7 (70%)
Care or nursing home		7 (70%)
Hospital		4 (40%)
<i>Experience per stage of disease progression</i>		
Experience in care for people with mild to moderate dementia		1 (10%)
Experience in care for people at all stages of dementia		9 (90%)

518

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 identified:	Scope	Stakeholder		Stage			Setting		
		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
Positive outcome domains (n=8):									
Improving posture	Includes sitting and standing posture.	x	x	x	x	x	x	-	x
Managing lower limb oedema	Fluid retention in the lower limbs.	-	x	-	-	x	x	-	x
Managing pressure ulcers	Preventing pressure ulcers and recovering skin integrity.	x	x	x	x	x	x	-	x
Preventing incontinence	Regularly using the toilet, by mobilising to the toilet or commode instead of using a pad.	-	x	-	-	x	x	-	x
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	x	x	x	x	-	x
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	x	x	x	x	x	x
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	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	x	x	x	x	x	-
Negative outcome domains or risks of physical activity (n=2):									
Eating or drinking	Eating or drinking something that should not be ingested, by confusing it with real food or drink.	x	x	x	x	x	x	-	-

something harmful

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). - x - x x - x -

520

521 “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
522 outcome domain has been identified in that context. Boxes identified with “-” indicate that an outcome domain has not 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)

Outcome domain identified:	Scope	Stakeholder		Stage			Setting		
		Prof. and researchers	Patients and carers	Mild to moderate	Moderate to severe	Severe	Community	Institution	Hospital
Positive outcome domains (n=4)									
Carer mobility	Carer mobility and balance, ability to walk with less joint pain.	x	x	x	x	x	x	-	-
Carer mood	Simply described as “carer mood”.	x	-	-	x	-	x	-	-
Carer quality of life	Carer wellbeing and quality of life. At times linked to carer burden.	x	-	x	x	x	x	-	x
Carer sleep	Improved carer sleep quality.	x	-	-	x	-	x	-	-
Negative outcome domains or risks of physical activity (n=5)									

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	-	x	x	x	x	x	-
Discovering cysts	Ganglion cyst.	x	-	x	-	-	x	-	-
Feeling dizzy, nauseous or fainting	Feeling dizzy, nauseous or light-headed. Having a syncopal episode.	x	-	x	x	x	x	-	-
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	-	x	x	x	x	x	-
Moving into care	Being placed into an institution for permanent full-time care.	x	-	x	x	x	x	-	-

526

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

528 *outcome domain has not been identified in that particular context.*

529

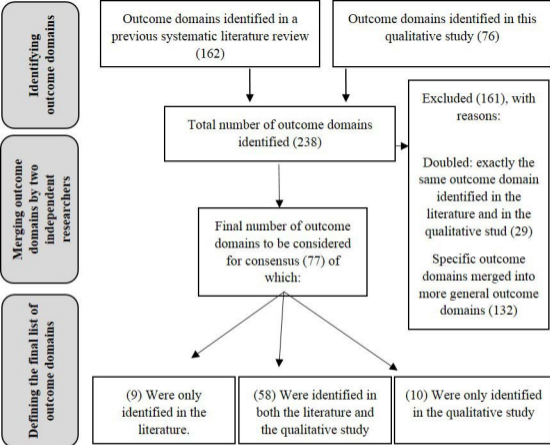


Figure 1- Flowchart of the development of final list of outcome domains to be considered in the next phase: consensus study.

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.	x	x	x	x	x	x	x	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	x	x	x	x	x	x
<u>Reframing and revisiting the person with dementia</u>	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	x	x	x	x	x	-
THEME: Delivering good quality care									
Adhering to activity	The extent to which an activity is completed according to a pre-set criteria of duration, frequency and intensity.	x	x	x	x	x	x	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	x	x	x	x	x	x	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.*