

QUALITATIVE PAPER

The facilitators and barriers to improving functional activity and wellbeing in people with dementia: a qualitative study from the process evaluation of Promoting Activity, Independence and Stability in Early Dementia (PrAISED)

CLAUDIO DI LORITO¹, VERONIKA VAN DER WARDT², KRISTIAN POLLOCK³, LOUISE HOWE⁴, VICKY BOOTH^{4,5}, PIP LOGAN⁴, JOHN GLADMAN⁴, TAHIR MASUD⁵, ROSHAN DAS NAIR⁶, SARAH GOLDBERG³, KAVITA VEDHARA⁴, REBECCA O'BRIEN⁴, EMMA ADAMS⁴, ALISON COWLEY^{4,5}, ALESSANDRO BOSCO⁷, JENNIE HANCOX⁸, CLARE BURGON³, RUPINDER BAJWA⁴, JULIETTE LOCK⁴, ANNABELLE LONG⁴, MAUREEN GODFREY⁴, MARIANNE DUNLOP⁴, ROWAN H. HARWOOD³

¹Division of Primary Care and Population Health, University College London, UK

²Institute of General Practice, University of Marburg, Germany

³School of Health Sciences, University of Nottingham, UK

⁴School of Medicine, University of Nottingham, UK

⁵Nottingham University Hospitals NHS Trust, UK

⁶Health Services Research, SINTEF Digital, Norway

⁷Primary Care Unit, University of Cambridge, UK

⁸School of Sport, Exercise and Health Sciences, Loughborough University, UK

Address correspondence to: Claudio Di Lorito, University College London, Research Department of Primary Care & Population Health, Centre for Ageing Population Studies, Royal Free Campus, Rowland Hill St. London, NW3 2PF, UK.

Tel: +4402031087687. Email: Claudio.dilorito@ucl.ac.uk

Abstract

Background: The PRomoting Activity, Independence and Stability in Early Dementia (PrAISED) study delivered an exercise and functional activity programme to participants living with dementia. A Randomised Controlled Trial showed no measurable benefits in activities of daily living, physical activity or quality of life.

Objective: To explore participants' responses to PrAISED and explain why an intervention that might be expected to have produced measurable health gains did not do so.

Methods: A process evaluation using qualitative methods, comprising interviews and researcher notes.

Setting: Data were collected in participants' homes or remotely by telephone or videoconferencing.

Sample: A total of 88 interviews were conducted with 44 participants living with dementia ($n = 32$ intervention group; $n = 12$ control group) and 39 caregivers. A total of 69 interviews were conducted with 26 therapists.

Results: Participants valued the intervention as proactively addressing health issues that were of concern to them, and as a source of social contact, interaction, information and advice. Facilitators to achieving positive outcomes included perceiving progress towards desired goals, positive expectations, therapists' skills and rapport with participants, and caregiver support. Barriers included: cognitive impairment, which prevented independent engagement and carry-over between sessions; chronic physical health problems and intercurrent acute illness and injury; 'tapering' (progressively infrequent supervision intended to help develop habits and independent activity); and the COVID-19 pandemic.

Conclusions: Self-directed interventions may not be appropriate in the context of dementia, even in the mild stages of the condition. Dementia-specific factors affected outcomes including caregiver support, rapport with therapists, availability of supervision, motivational factors and the limitations of remote delivery. The effects of cognitive impairment, multimorbidity and frailty overwhelmed any positive impact of the intervention. Maintenance of functional ability is valued, but in the face of inevitable progression of disease, other less tangible outcomes become important, challenging how we frame 'health gain' and trial outcomes.

Keywords: dementia, process evaluation, exercise, qualitative research, older people

Key Points

- Self-directed interventions may not be appropriate in the context of dementia, even in the mild stages of the condition.
- Dementia-specific factors affect intervention outcomes including cognitive impairment and motivational issues.
- Effects of cognitive impairment, multimorbidity and frailty overwhelm positive impact of the intervention.
- Maintenance of functional ability is valued, but in dementia, other less tangible outcomes become important.
- There is a need to reframe 'health gain' and trial outcomes in dementia.

Introduction

Dementia is a neurodegenerative condition characterised by a progressive deterioration of both cognitive and motor functioning leading to a loss of independence, reduced quality of life and increased risk of injuries and hospitalisation [1–8]. A number of functional activity, physical activity and exercise intervention programmes have been developed to help people living with dementia to maintain their independence for longer [9, 10], including the Promoting Activity, Independence and Stability in Early Dementia (PrAISED) intervention [11, 12].

We evaluated the PrAISED intervention in a Randomised Controlled Trial (RCT), randomising.

A total of 365 participants across five sites in England to an intervention arm or a control group (brief falls assessment and advice) [12]. Participants in the intervention arm took part in an individually tailored programme comprising physical exercises (i.e. progressive strength, balance and dual task); functional activities (activities of daily living, ADL, with an element of physical activity, such as going shopping); promotion of inclusion in community life (e.g. signposting physical exercise group classes); risk enablement (positive risk-taking); and environmental assessment (accessibility and safety issues at home). They received up to 50 home therapy sessions over 12-months from a multidisciplinary team comprising physiotherapists (PTs), occupational therapists (OTs) and rehabilitation support workers (RSWs) ($n = 68$) [12]. The sessions were intended to teach and supervise exercise and functional activities, monitor progress and adjust the programme. Participants were asked to undertake exercise activities between therapy sessions.

PrAISED delivered 5,356 therapy visits between October 2018 and June 2022. Participants recorded exercise on a monthly calendar and reported undertaking a mean of 121 min/week of PrAISED exercise. The RCT showed no measurable benefits in ADL, increased physical activity,

quality of life or any other of the battery of health status measures studied [13].

PrAISED was a complex intervention because of its many interacting components (functional and physical exercises), the number of agents involved (people living with dementia, caregivers, therapists) and the different contexts (social and cultural) within which the programme was implemented [14]. When evaluating complex interventions, process evaluations are essential complements to RCTs [14]. A process evaluation identifies mechanisms of impact: (participant-level factors that affect the emergence of outcomes) and contextual factors (characteristics of the physical, cultural and social contexts) that affect the emergence of outcomes.

The aims of the PrAISED process evaluation were to investigate participants' responses to the programme, and to explain why an intervention that might be expected to have produced measurable health gains did not do so.

Methods

This study followed Medical Research Council guidance for process evaluation [14]. The protocols have been published [15, 16]. We report on implementation in terms of reach, dose, fidelity and adaptation elsewhere [13]. This study adopted a qualitative design, based on interviews and researchers' notes.

Sample

A sub-sample of participants living with dementia and their caregivers were purposively selected from the PrAISED RCT to obtain a diverse sample in relation to age, gender, ethnicity, location, relationship status and living status. Participants from the intervention and control groups were selected for comparison purposes. All participants living with dementia were able to give consent. Therapists were recruited based on their availability. Sample size was based

on conceptual density (i.e. gathering data until a *sufficient depth* of understanding was reached) [17], which was agreed upon by two researchers (CDL and VvdW).

Data collection

Semi-structured interviews were conducted with participants living with dementia and their caregivers (as dyads or individually, depending on preference), and with therapists (individually).

Two sets of interviews took place in the participants' homes and in the therapists' offices (Appendix 1): pre and during the COVID-19 pandemic. For the first set, the interviews took place at month 6 and month 12 of participants' involvement in PrAISED. Interview topic guides (Appendices 2 and 3) were co-developed with two Patient and Public Involvement (PPI) co-researchers with lived experience of caring for someone living with dementia (MG and MD) to ensure that the interview schedule was relevant, meaningful and accessible. The topic guide was informed by the Physical Activity Behaviour change Theoretical model in dementia (PHYT-in-dementia) [18, 19], which identified a set of factors mediating intervention experience/outcomes, e.g. autonomy/independence, motivation. For each factor, several prompts were developed, but a flexible approach was adopted to explore themes emerging during the interviews. All interviews were conducted by the first author, and eight interviews with participants and caregivers were co-facilitated with one PPI co-researcher. Written consent from all participants was obtained prior to the interview.

The second set of interviews, taking place following COVID-19 lockdown in England (March 2020), aimed to monitor the impact of restrictions on the delivery and reception of PrAISED. The original interview topic guides were adapted (Appendices 4 and 5). Interviews were conducted by telephone or video call and were undertaken by the first author. Verbal consent from all interviewees was audio recorded.

Data analysis

All interviews were audio recorded, transcribed verbatim and anonymised. Transcripts were analysed through inductive thematic analysis [20]. CDL and two PPI co-researchers (MG and MD) examined the transcripts independently of each other and made annotations/reflections on emerging mechanisms of impact and contextual factors. The independent coders convened to discuss their annotations and create a tentative list of mechanisms of impact and contextual factors. The list was passed to a fourth (VvdW) and fifth researcher (AB), who provided feedback, which was integrated to finalise a coding scheme. This featured an operational definition for each mechanism of impact and contextual factor, data to be coded within each (for replicability), and participants' quotations (Supplement Table 1). Four co-authors (MG, MD, VvdW and KP) checked the final analysis.

Three co-authors (CDL, VvdW and RH) (independently of each other) included each identified mechanism of impact

and contextual factor into one of the two categories of facilitators and barriers. The three authors then convened to agree on a definitive list. Based on interview data and personal reflections that the co-researchers (CDL, MG and MD) annotated after each interview session, four case-study vignettes (Appendix 6) and an ecological system model (Figure 1) were produced to illustrate the complex interaction between barriers and facilitators in generating outcomes.

Ethics

The PrAISED RCT and process evaluation received ethical approval from the Bradford-Leeds Research Committee (18/YH/0059).

Results

A total of 88 interviews were conducted with 44 participants living with Mild Cognitive Impairment (MCI) or dementia (mean age: 79 years, 95% white ethnicity, 84% living alone, $n = 12$ control and $n = 32$ intervention group) and 39 caregivers (mean age: 72 years). The interviews were dyadic (i.e. participant living with dementia and caregiver) face-to-face ($n = 40$), dyadic on the phone ($n = 36$), individual (i.e. participant living with dementia only) on the telephone ($n = 10$) and dyadic on webcam ($n = 2$). A total of 69 interviews were conducted with 26 therapists ($n = 8$ PTs, $n = 8$ OTs, $n = 10$ RSWs; Supplement Table 2). In the following sections, we report themes with relevant quotations (P indicates participants living with dementia, C indicates caregivers and T identifies therapists).

General reception of the PrAISED programme

PrAISED was well received by participants and caregivers. Participants in the control group appreciated the brief falls assessment and advice provided by the team. Whilst some reported increased awareness of exercise and health, this did not have any substantial impact on their physical activity levels pre-PrAISED:

'We are more aware of our health, so I do think it's making a difference to our lifestyle, but not as much as it should, we would be better if we did more exercise' C15.

'We were doing it before anyway Before PrAISED. We were all over the parks and Attenborough and everywhere' Participant' P10.

When invited to give feedback on PrAISED during the interviews, 23/29 (80%) participants in the intervention group reported a very positive experience with PrAISED and stated that the programme had made a positive change in their lives. An example of the positive impact of PrAISED is illustrated by John's story: <https://vimeo.com/372693414/3f698b5f60>. Participants and caregivers reported they valued therapist visits for the opportunity to improve or maintain physical ability and boost their confidence:

'It did make a difference, because at the start of the study I could only walk a short distance; whereas at the end of the study I could walk round the block, and it gave me quite a lot of confidence' P12.

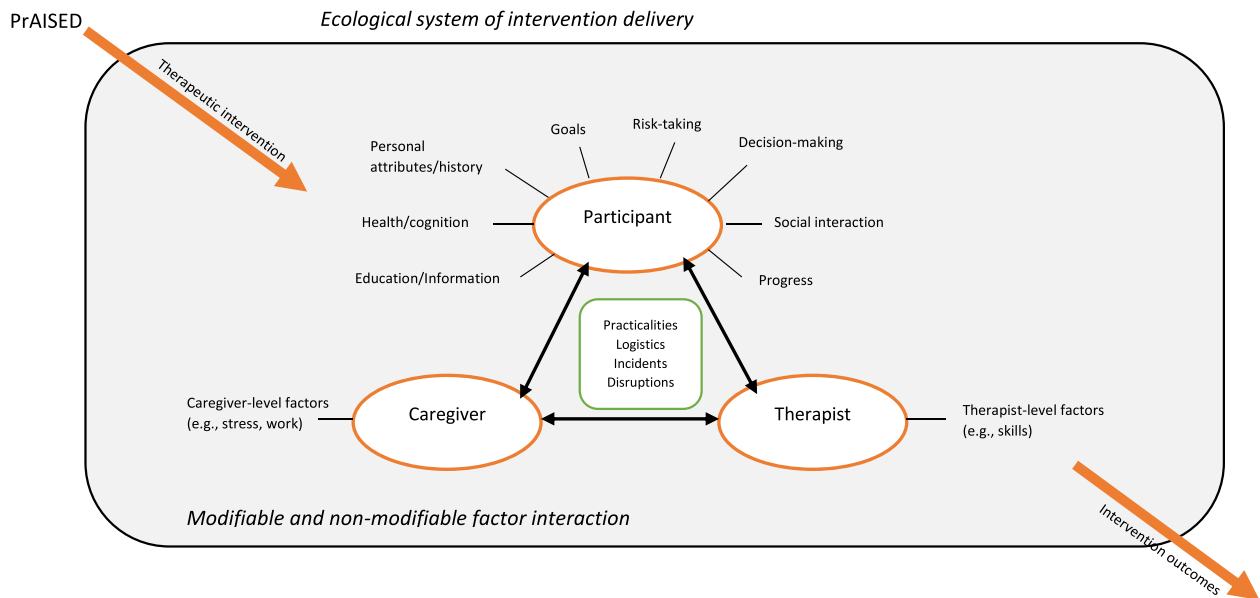


Figure 1. Ecological system model.

Therapy visits were an opportunity for participants and caregivers to develop awareness and knowledge about exercise and dementia, as well as to learn about opportunities for activities and resources available in the community:

'I think doing these things has enabled me now to think about it and challenge myself to improve my fitness and keep on doing things and hopefully whatever is the problem, it doesn't develop into dementia' P16.

'E. (therapist) who used to come, she told us about it (exercise class in the community). Apparently, it's been going for about two years, but we didn't know anything about it. So, he goes there every week on a Wednesday now for an hour. So that does him good' C03.

Participants appreciated that therapists would arrange modifications to the house (e.g. installation of chair lifts) to make it more dementia-friendly:

'A. (therapist) arranged for him to have a perching stool, because he did try to do some potatoes one day. Well, he did so many and then he couldn't stand up any longer. And E. (another therapist) fixed it to the right height and everything. I don't think we can ask for anything better really' C04.

The social interaction and support presented by therapy visits brought genuine affirmation and respect for the participants' personhood. The interactions were described as deep and intimate:

'It gave him something to look forward to. It was a little bit of structure to know that someone was coming every so often' C12.

'I can say to the therapist if he's not in a right mood today, I can talk to them, you know what I mean, and I'll have a laugh' C14.

'Being with R. (therapist) is very pleasant company, so that is good. I will miss his friendship and his ability to help me maintain what little memory I've got and the incentive that he gave me to continue physical exercise' P18.

As a result of positive interactions and support from therapists, the participants were more willing/motivated to initiate and maintain exercise:

'When the support worker comes along, she encourages you to do them doesn't she? You wouldn't say no I'm not going to do them really' P13.

Facilitators to achieving positive intervention outcomes

The therapists were instrumental in supporting participants to achieve outcomes. Their ability to encourage, motivate and instil confidence to participants was highly regarded:

'She (PT) makes you feel as if you can do this, and this is a good thing to do and really gets you started and motivates you to start with' C03.

Good rapport between therapists and participants/caregivers and the social element of therapy visits were key factors for positive outcomes. Feelings of loneliness or social exclusion of participants/caregivers were common, due to mobility issues, symptoms of dementia, demographic reasons (close friends passing away, caregiving responsibilities); therapy visits came to be seen as a change from the usual routine, an opportunity for human interaction at a meaningful level:

'It was mentally stimulating for him, and it was something to look forward to. It was someone to come and chat, it was someone different to me being in the house. And I think you get to befriend that person when she comes' C12.

The therapy team provided a source of knowledge about dementia care, social care, pensions, tax exemption, medications, community groups, support, respite and care planning. Participants and caregivers were often unaware of resources, activities and initiatives being offered in the community. The knowledge of the therapy team often bridged the gap between services and users. Receiving

information about the potential benefits of the intervention was a key facilitator to ensuring participants' commitment to PrAISED, as participants might have vague ideas about the nature and purpose of the intervention:

'The participant could do with understanding the link between exercise and mood and feelings of wellbeing and potential improvements generally in cognition. That might harness motivation'. Therapist' T57.

Caregivers were also facilitators to achieving positive outcomes. Given the support needs that dementia entails, relying on the caregiver to maintain exercise/activity levels in between therapy visits was common. Some caregivers were able and willing to provide support, as they anticipated the potential benefits of the programme, which extended to themselves and to their relationship with the person they cared for:

'I go with him because I don't think he could cope with that. But by me going with him, I chat to other people that have got similar problems. And so, in a way I quite look forward to going because rather than the little circle I've already got, I see a little bit bigger circle' C02.

Expectations and potential goals to be achieved as a result of taking part in PrAISED was linked to positive outcomes. For some, there was an expectation that the programme would improve mobility and independence:

'Hopefully I'm going to get better. My legs are going to strengthen. And I will be able to get up and walk about unaided, if you like' P02.

Tailoring the programme and goals according to participants' interests with a focus on achieving meaningful goals/purposeful activities (e.g. helping participants to continue doing the activities they enjoy doing) was a booster to some participants' commitment to PrAISED, which resulted in positive outcomes:

'I really just want to keep us as active as I possibly can. We've got great grandchildren, which I like to see as often as possible. I can't pick them up and carry them about now' P06.

Some participant-level variables were linked to positive outcomes. Experiencing benefits as a result of doing physical exercise promoted a sense of achievement. Some participants recognised benefits such as improvement in their physical health and coming to terms with dementia. Reaching goals that seemed impossible just months before boosted participants' commitment to continue with the exercises, by progressing their intensity and setting new goals:

'I'm feeling more flexible now. I'm accepting it a bit more. I don't get a sharp pain or anything. And if I keep moving and doing something I seem to get away with it all right' P07.

Barriers to achieving positive intervention outcomes

A prominent factor linked to negative intervention outcomes was pre-existing, often chronic physical health conditions. Participants' physical health greatly affected delivery and response to PrAISED, as well as which benefits could be achieved following the intervention. Chronic health conditions, such as arthritis and its consequent pain, had

a particularly negative effect on the ability to perform the physical activities set out in the programme. Whilst some participants showed resilience by adopting compensatory strategies, such as concentrating physical activity on the days when they felt better, many reported either being unable to do the exercises and activities set out in their programme or being unmotivated to engage with no prospect of improvement:

'I was wondering whether I'd give up altogether because I've seen three different doctors at different times, and they can't do anything with it (pain) and it just comes and goes. Well, if it's going to do that it's a bit pointless isn't it, my trying to strengthen something that comes and goes' P05.

Cognitive impairment and symptoms including apathy, forgetfulness and fluctuations in wellbeing posed a particular barrier to the intervention. A common challenge was that memory impairment would cause the participants to forget they were committed to the exercise programme. Thus, the therapists found it difficult to progress participants towards final intervention goals:

'I don't know if when I arrive, she's (participant) going to be like "R. lovely, let's do the exercises", and be really on the ball, or I could go in, she could be quite anxious about me being there because she needs to go and pick up the kids from school. And so that's why I can't plan a session' T58.

Another issue experienced in PrAISED was around tapering therapists' support over time. Participants contended that habit formation was challenging given the support needs of people living with dementia, and that reducing the number of visits over time was inevitably linked to a reduction in the amount of physical exercise and obtainment of associated benefits:

'R. (therapist) came twice a week, once a week and then once a fortnight. And then all of a sudden it was once a month. And when it went down to once a month it didn't keep me on my toes to religiously do the exercises' P16.

This was particularly challenging for participants who lived alone who could not count on the support or reminders of caregivers outside therapy sessions. Some personal characteristics of the participant also presented barriers. Whilst a sense of competitiveness could push some participants to aspire to achieve more from the programme, many tended to compare their present self to past achievements. This generated a sense of defeat, which was hard to challenge. The trend was particularly visible in male participants who had a previous career that emphasised physical ability and performance excellence:

'The fact that I used to swim 50 lengths every time I went and now the thought of being able to do five or six isn't really a motivation' P03.

Another barrier was the unrealistic or unachievable expectations of some participants, which would set them up for failure. Unrealistic expectations might have been generated by wishful thinking about 'curing' dementia or miscommunication with the therapists:

'The thing is mum had been told that she could go with her scooter on the bus, and the truth is you can't. The difficulty

with that is they give you these ideas that it's all possible, and realistically it's not' C05.

The realisation that the unachievable goal had not been obtained would inevitably affect participant's adherence to the intervention and led to not achieving positive outcomes. Some caregiver factors presented barriers, such as their views on dementia and attitudes towards risk. Some caregivers feared that the person they cared for might be at risk of falling or harm when doing PrAISED exercises or activities in between therapy visits. The anxiety was particularly acute where there was a history of previous falls and injuries. They would become instinctively risk-averse and potential gatekeepers to the participant levels of activity:

I've seen what happens when he falls, and I've got that awful fear. And all I think about is oh my god he's going to fall, he'd going to fall. I think I couldn't walk him round the block, I'd be an absolute, well I would, I'd be shaking by the time I got back' C12.

Given the support needs of participants to be able to maintain exercise/activity in between therapy sessions, carer input (and care responsibilities) would inevitably increase as a result of PrAISED. Some caregivers felt that the added burden on top of existing caring duties was too much, and they could not fully support the participant:

A participant, it was his wife who said to me I can't support my husband to engage in the programme as much as I wanted to. It's causing me stress, too much pressure, I'm going to have to withdraw. So, it wasn't actually the participant, but it was his wife' T57.

Several practical and logistical factors also posed barriers to a successful intervention. Life often 'got in the way' of doing the exercise programme. The participants and caregivers often found it difficult to find time to be allocated to the programme, caught as they were in their daily routines:

We actually are very poor at keeping up with that because your life is taken over by your normal routine. Our normal routine is actually quite busy' C15.

Living alone posed a barrier as well, because of the lack of reminders to initiate and support to facilitate exercise/activity. Accessibility of home for exercise or activity, and lack of opportunities in the community were also accountable. Some participants reported they struggled to achieve goals that involved outdoor activities, given risks and accessibility. This was a particular concern for people with dementia living alone or in rural areas:

I cycle in the gym, but I don't go anywhere. I find these roads quite frightening. There are so many potholes, the traffic is very big here, in the summertime lorries, tractors, great big farm implements' P15.

Unexpected events beyond the control of the therapy team posed barriers to the intervention, including injuries, hospitalisations, medications, holidays and other life events, as the progress made could easily be halted or lost:

That (new medications' side effects) altered the programme as well because we had to get over that. And I think since then you've sort of lost' C12.

A unique circumstance that disrupted the intervention was the COVID-19 pandemic. Some participants were negatively affected by the lack of face-to-face support and lost the progress they had previously made. Remote delivery lacked the human connection that had been instrumental to the success of PrAISED pre-COVID-19 pandemic:

From Mum's point of view, not used to using these types of technologies it's not just like having someone sat in the armchair next to you having a chat. It's just not what she is used to' C21.

Remote support presented specific barriers relating to cognitive impairment. For example, not seeing a face during telephone sessions prevented participants from recalling who they were talking to. Remote delivery of PrAISED proved challenging for caregivers too, who experienced an increase in their support role in the lack of in-home visits from the therapists. Their respite time reduced, as caregivers reported needing to do the exercise routine with participants:

I think I would prefer her (therapist) to come because I think when she was here, I could go into another room if necessary and do a job or two' C28.

Ecological system of PrAISED

It is important to emphasise that PrAISED was a complex intervention, and facilitators and barriers were generated through a complex interaction. Depending on the individual participant and the context, some facilitating mechanisms could also become barriers to intervention outcomes (and vice versa). For example, good rapport with therapist could be productive or counterproductive. Some participants might develop a habit of physical exercise though good rapport with the therapists that would be maintained post-PrAISED, whilst others might develop overdependency and give up exercise once therapist support was discontinued.

Some facilitators/barriers were dependent on PrAISED and modifiable (e.g. therapist's support), whilst some others such as participants' history, and unexpected events were not preventable or modifiable by the study team. However, they inevitably affected intervention outcomes.

No single facilitator or barrier was at play in equal measures in different participants. Different combinations/-dosage of facilitators/barriers produced different outcomes (e.g. pain + loss of confidence vs. pain + loss of confidence + risk-aversion). They added or detracted from each other within a complex ecological system. The model in Figure 1 illustrates this complex interaction. As a result of this complexity, each participant had a distinct experience of the intervention. Some participants had a very positive response to and experience of PrAISED, whilst others less so. The case study vignettes (Appendix 6) were developed to reflect the diversity of experiences of PrAISED.

Discussion

The aims of the PrAISED process evaluation were to investigate the reception of the programme and explain findings from the RCT [13] by identifying facilitators and barriers to achieving positive outcomes.

The PrAISED RCT found that the primary outcome of Disability Assessment for Dementia (DAD) [21] after 12 months was no different between intervention and control groups (Cohen's *d* effect size -0.06 , 95% CI -0.26 , 0.15 ; $P = 0.5$) [13]. An important factor that might have led to these outcomes was the difficulty in maintaining exercise/activity levels independently in the intervention group between therapy sessions and over time as the professional supervision reduced. PrAISED therapy visits were tapered off over time, based on the idea that through habit formation, the participants would sustain exercise/activity independently. Habit formation was found to be at odds with the cognitive deterioration and apathy typical of dementia [22]. For example, participants could be reluctant or forget to keep active. Therapists reported a particular challenge linked to memory problems, whereby motivation for the intervention had to be developed from scratch at each session. This would make setting and achieving goals difficult, reduce margin for progress and had a direct impact on intervention outcomes. An important implication for future practice is that it is unlikely that an intervention can be successful with this population unless there is a recognition that support from significant others or therapy teams [23–26] is a pre-requisite for success. This also highlights the issue of maintenance of physical activity in those who live alone or lack support.

Another potential explanation for negative outcomes was the COVID-19 pandemic and its consequent lockdown, which occurred mid-RCT, and required PrAISED therapy sessions to be adapted from face-to-face in-home to remote delivery through telephone or videoconferencing. Challenges linked to effective remote delivery included logistical factors, such as information technology accessibility and use. In line with our previous findings [27, 28], this study found that remote support for some people living with dementia was feasible, but it required pre-conditions that in most cases were lacking, such as proper infrastructure, both in terms of support to use technology and capacity building (e.g. availability of an internet connection). Whilst this may be less of an issue in the future where older people will have used IT throughout their lives, they currently need developing. This will ensure that interventions requiring remote or hybrid (face-to-face/remote) delivery (e.g. due to remote location or mobility issues) [29, 30] are designed or supported, so that people living with dementia are offered equitable access.

Despite the RCT results, participant responses to the intervention were overall positive. Participants valued the intervention as proactively addressing health issues that were of concern to them, and as a source of social contact, interaction, information and advice. This might indicate that the PrAISED RCT may not have identified outcomes (and benefits) that really mattered to participants and as a result to capture/measure them.

Benefits in the areas of social contact, interaction, information and advice were gained largely due to therapists'

hard and soft skills. Rehabilitation work with people living with dementia is complex and challenging, requiring specialist knowledge and skills to address the complex and distinct needs of this population [31]. Alongside therapists' professional assets, the participants and caregivers appreciated a set of 'soft' skills intrinsic to individual therapists that were instrumental to enhance intervention experience and engagement, including empathy, positivity, humanness, active listening and showing commitment to the programme/participants.

Initially, good rapport was intended as a tool to maximise intervention uptake. In time (partly due to the social restrictions imposed by COVID-19), participants came to consider therapy visits as a means for social interaction with the therapist, and advice, something that they greatly valued. Often, the emphasis came to be placed on the social occasion of the therapy visits, rather than on exercise. The implication for future interventions is to acknowledge that social exclusion is common amongst people living with dementia (and caregivers) and that integrating intervention protocols with strategies fulfilling participants' needs for meaningful intimate human connectedness will boost their experience of the intervention. Such strategies could include, as per the PrAISED example, therapists linking participants to opportunities for social inclusion in the community (and measures to detect greater or less social inclusion).

Another crucial factor for intervention success was caregiver support for participants to be able to fully engage in the intervention. An example of the impact of caregiver support was embracing positive risk-taking, which could encourage participants' activity levels. An effective way to ensure caregiver support was to address (justified or unjustified) concerns, resistance and pre-conceptions about physical activities in dementia. Another way to garner caregiver endorsement was to build their capability to provide support to the person, as it was recognised that this would increase care burden. Therefore, for any future successful intervention programme, caregivers' emotional, physical and financial burden [32–44] should be acknowledged and effectively addressed through a holistic approach, where the caregiver is also considered as the recipient of a package of support/care.

Strengths and limitations

- This study presents novel data and implications for research, clinical practice and a framework for future process evaluations.
- The extraordinary circumstances of the COVID-19 pandemic presented problems for both intervention delivery and research, but resulted in novel data [45, 46].
- We used an innovative model of Patient and Public Involvement co-research [47].
- The evaluating team was mostly but not fully independent of the intervention delivery team. Risk of bias was

minimised through the involvement of multiple coders in the analysis of the interviews external to the delivery team.

- Data generated through the interviews might not reflect the experience of all participants in PrAISED given the relatively small sample. The process evaluation adopted purposive sampling to ensure representation of different experiences.
- In dyadic interviews, some caregivers were reserved in discussing sensitive subjects in the presence of the person they cared for. Whilst recognising this limitation, the team also believed that existing dynamics between caregiver and participant did not need addressing, as they represented the bedrock (i.e. ecological system) on which the intervention was delivered.

Summary and conclusion

The PrAISED intervention was liked by participants with dementia and their family caregivers. From process evaluation interviews, it can be determined that several aspects of the strategy to promote engagement and motivation were successful, including delivery at home by expert health-care professional staff, goal setting, tailoring according to interests, co-morbidities and abilities, a focus on achieving practical and useful activities, and close involvement of family carers. It can also be inferred that the use of tapered supervision to encourage independent activity was ineffective and may have diminished exercise undertaken over time. Family and other carers were supportive and helpful, despite their own experience of strain and ill health, and their own 'respite' time being diminished. Positive risk taking was met with some scepticism, but efforts to increase confidence and planning to minimise risk were successful.

We included a group with relatively mild cognitive impairment, but forgetfulness and apathy proved to be major barriers to undertaking activities without direct supervision, carry-over between sessions and subsequently progression. This was a particular problem for people living alone. Co-morbidities, illnesses and injuries and other disruptions were frequent and set back functional gains. In particular, the COVID-19 pandemic and ongoing restrictions, substantially interfered with intervention delivery for many participants, despite efforts to deliver the intervention remotely. Access to community facilities was curtailed or became less attractive. Insofar as the intervention was successful, it was in ways that were not specifically intended or anticipated, including developing therapeutic relationships, affirmation of personhood, agency and hope, social contact and occupation, information giving and advice. Overall levels of engagement with the programme were satisfactory or good.

We must therefore conclude that the content of the intervention was ineffective, and/or progression and symptoms of dementia or intercurrent health crises reduced compliance and as a result overwhelmed any beneficial effects. This all suggests that self-directed interventions may not be appropriate in the context of dementia, even in the mild stages of the condition. It also raises the question of whether

subjective wellbeing and health gain in dementia is achieved more through socio-emotional-relational opportunities/interventions than through physical exercise per se.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

Acknowledgements: The PrAISED team would like to thank Katarzyna Kowalewska for her invaluable support in this study.

Declaration of Conflicts of Interest: None.

Declaration of Sources of Funding: This work was funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research Programme (Reference Number RP-PG-0614-20,007). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Data Availability Statement: The data underlying this article will be shared on reasonable request on the corresponding author.

References

1. Martyr A, Clare L. Executive function and activities of daily living in Alzheimer's disease: a correlational meta-analysis. *Dement Geriatr Cogn Disord* 2012; 33: 189–203.
2. Giebel CM, Sutcliffe C, Stolt M *et al.* Deterioration of basic activities of daily living and their impact on quality of life across different cognitive stages of dementia: a European study. *Int Psychogeriatr* 2014; 26: 1283–93.
3. Giebel CM, Sutcliffe C, Challis D. Activities of daily living and quality of life across different stages of dementia: a UK study. *Aging Ment Health* 2015; 19: 63–71.
4. Alzheimer's Research UK (2019). About dementia. Available online at: https://www.alzheimersresearchuk.org/about-dementia/?gclid=Cj0KCQjw3JXtBRC8ARIsAEBHg4myuYea_hFMLCcSGLr-flQxznmdb-dObW2gXc5MUN9o_dfNw5wwI5EwaAvH6EALw_wcB (accessed on 26 March 2020).
5. Muir SW, Gopaul K, Montero Odasso MM. The role of cognitive impairment in fall risk among older adults: a systematic review and meta-analysis. *Age Ageing* 2012; 41: 299–308.
6. Delbaere K, Kochan NA, Close JC *et al.* Mild cognitive impairment as a predictor of falls in community-dwelling older people. *Am J Geriatr Psychiatry* 2012; 20: 845–53.
7. Kallin K, Gustafson Y, Sandman PO, Karlsson S. Factors associated with falls among older, cognitively impaired people in geriatric care settings: a population-based study. *Am J Geriatr Psychiatry* 2005; 13: 501–9.
8. Tinetti ME, Speechley M, Ginter SF. Risk factors for falls among elderly persons living in the community. *New England J Med* 1988; 319: 1701–7.
9. Pitkälä KH, Pöysti MM, Laakkonen ML *et al.* Effects of the Finnish Alzheimer disease exercise trial (FINALEX): a randomized controlled trial. *JAMA Intern Med* 2013; 173: 894–901.
10. Prick AE, De Lange J, Scherder E *et al.* The effects of a multi-component dyadic intervention with physical exercise on the

- cognitive functioning of people with dementia: a randomized controlled trial. *J Aging Phys Act* 2017; 25: 539–52.
11. Booth V, Harwood RH, Hood-Moore V *et al.* Promoting activity, independence and stability in early dementia and mild cognitive impairment (PrAISED): development of an intervention for people with mild cognitive impairment and dementia. *Clin Rehabil* 2018; 32: 855–64.
 12. Bajwa RK, Goldberg SE, Van der Wardt V *et al.* A randomised controlled trial of an exercise intervention promoting activity, independence and stability in older adults with mild cognitive impairment and early dementia (PrAISED)-a protocol. *Trials* 2019; 20: 1–1. <https://doi.org/10.1186/s13063-019-3871-9>.
 13. Harwood RH, Goldberg SE, Brand A *et al.* Promoting activity, independence and stability in early dementia and mild cognitive impairment (PrAISED): a randomised controlled trial. *MedRxiv* 2022: 12.
 14. Moore GF, Audrey S, Barker M *et al.* Process evaluation of complex interventions: Medical Research Council guidance. *BMJ* 2015; 350: 1–133. <https://doi.org/10.1136/bmj.h1258>.
 15. Di Lorito C, Godfrey M, Dunlop M *et al.* Adding to the knowledge on patient and public involvement: reflections from an experience of co-research with carers of people with dementia. *Health Expect* 2020; 23: 691–706.
 16. Di Lorito C, Pollock K, Harwood R *et al.* Protocol for the process evaluation of the promoting activity, independence and stability in early dementia and mild cognitive impairment (PrAISED 2) randomised controlled trial. *Maturitas* 2019; 122: 8–21.
 17. Nelson J. Using conceptual depth criteria: addressing the challenge of reaching saturation in qualitative research. *Qualitative Res* 2017; 17: 554–70.
 18. Di Lorito C, Pollock K, Harwood R *et al.* A scoping review of behaviour change theories in adults without dementia to adapt and develop the 'PHYT in dementia', a model promoting physical activity in people with dementia. *Maturitas* 2019; 121: 101–13.
 19. Di Lorito C, Bosco A, Pollock K *et al.* External validation of the 'PHYT in dementia', a theoretical model promoting physical activity in people with dementia. *Int J Environ Res Public Health* 2020; 17: 1544. <https://doi.org/10.3390/ijerph17051544>.
 20. Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qualitative Res Sport Exercise Health* 2019; 11: 589–97.
 21. Gélinas I, Gauthier L, McIntyre M, Gauthier S. Development of a functional measure for persons with Alzheimer's disease: the disability assessment for dementia. *Am J Occup Ther* 1999; 53: 471–81.
 22. Williams AK. Motivation and dementia. *Topics Geriatric Rehabilitation* 2005; 21: 123–6.
 23. Monahan DJ. Assessment of dementia patients and their families: an ecological-family-centered approach. *Health Soc Work* 1993; 18: 123–31.
 24. Haupt M, Karger A, Jänner M. Improvement of agitation and anxiety in demented patients after psychoeducative group intervention with their caregivers. *Int J Geriatr Psychiatry* 2000; 15: 1125–9.
 25. Rosen J, Mittal V, Mulsant BH, Degenholtz H, Castle N, Fox D. Educating the families of nursing home residents: a pilot study using a computer-based system. *J Am Med Dir Assoc* 2003; 4: 128–34.
 26. Perry JA, Olshansky EF, Koop PM, Cardea JM. A family's coming to terms with Alzheimer's disease. *West J Nurs Res* 1996; 18: 12–28.
 27. Di Lorito C, Duff C, Rogers C *et al.* Tele-rehabilitation for people with dementia during the COVID-19 pandemic: a case-study from England. *Int J Environ Res Public Health* 2021; 18: 1717. <https://doi.org/10.3390/ijerph18041717>.
 28. Cowley A, Booth V, Di Lorito C *et al.* A qualitative study on the experiences of therapists delivering the promoting activity, independence and stability in early dementia (PrAISED) intervention during the COVID-19 pandemic. *J Alzheimers Dis* 2022; 91: 203–14.
 29. Sekhon H, Sekhon K, Launay C *et al.* Telemedicine and the rural dementia population: a systematic review. *Maturitas* 2021; 143: 105–14.
 30. Bauer M, Fetherstonhaugh D, Blackberry I, Farmer J, Wilding C. Identifying support needs to improve rural dementia services for people with dementia and their carers: a consultation study in Victoria. *Aus Aus J Rural Health* 2019; 27: 22–7.
 31. Quick SM, Snowdon DA, Lawler K, McGinley JL, Soh SE, Callisaya ML. Physical therapist and physical therapist student knowledge, confidence, attitudes, and beliefs about providing Care for People with dementia: a mixed-methods systematic review. *Phys Ther* 2022; 102. <https://doi.org/10.1093/ptj/pzac010>.
 32. La Fontaine J, Read K, Brooker D *et al.* The experiences, needs and outcomes for caregivers of people with dementia: literature review. 1–106.
 33. Campbell P, Wright J, Oyeboode J *et al.* Determinants of burden in those who care for someone with dementia. *Int J Geriatric Psychiat*: *J Psychiat Late Life Allied Sci* 2008; 23: 1078–85.
 34. Cooper C, Katona C, Orrell M, Livingston G. Coping strategies and anxiety in caregivers of people with Alzheimer's disease: the LASER-AD study. *J Affect Disord* 2006; 90: 15–20.
 35. Gaugler JE, Roth DL, Haley WE, Mittelman MS. Can counseling and support reduce burden and depressive symptoms in caregivers of people with Alzheimer's disease during the transition to institutionalization? Results from the new York University caregiver intervention study. *J Am Geriatr Soc* 2008; 56: 421–8.
 36. Cooper C, Balamurali TB, Livingston G. A systematic review of the prevalence and covariates of anxiety in caregivers of people with dementia. *Int Psychogeriatr* 2007; 19: 175–95.
 37. Cooper C, Katona C, Orrell M, Livingston G. Coping strategies and anxiety in caregivers of people with Alzheimer's disease: the LASER-AD study. *J Affect Disord* 2006; 90: 15–20.
 38. Prince M, Graham N, Brodaty H *et al.* Care arrangements for people with dementia in developing countries. *Int J Geriatr Psychiatry* 2004; 19: 178–81.
 39. Schulz R, Martire LM. Family caregiving of persons with dementia: prevalence, health effects, and support strategies. *Am J Geriatr Psychiatry* 2004; 12: 240–9.
 40. Segerstrom SC, Schipper LJ, Greenberg RN. Caregiving, repetitive thought, and immune response to vaccination in older adults. *Brain Behav Immun* 2008; 22: 744–52.
 41. Vitaliano PP, Zhang J, Scanlan JM. Is caregiving hazardous to one's physical health? A meta-analysis. *Psychol Bull* 2003; 129: 946–72.
 42. Gaugler JE, Kane RL, Kane RA, Newcomer R. Unmet care needs and key outcomes in dementia. *J Am Geriatr Soc* 2005; 53: 2098–105.

43. Di Lorito C, Bosco A, Godfrey M *et al.* Mixed-methods study on caregiver strain, quality of life, and perceived health. *J Alzheimers Dis* 2021; 80: 799–811.
44. Greenwood N, Mezey G, Smith R. Social exclusion in adult informal carers: a systematic narrative review of the experiences of informal carers of people with dementia and mental illness. *Maturitas* 2018; 112: 39–45.
45. Di Lorito C, Masud T, Gladman J *et al.* Deconditioning in people living with dementia during the COVID-19 pandemic: qualitative study from the promoting activity, independence and stability in early dementia (PrAISED) process evaluation. *BMC Geriatr* 2021; 21: 1-10. <https://doi.org/10.1186/s12877-021-02451-z>.
46. Di Lorito C, van der Wardt V, O'Brien R *et al.* Impact of COVID-19 lockdown on physical exercise among participants receiving the promoting activity, independence and stability in early dementia (PrAISED) intervention: a repeated measure study. *BMC Geriatr* 2022; 22: 1–7. <https://doi.org/10.1186/s12877-022-03239-5>
47. Di Lorito C, Godfrey M, Dunlop M *et al.* Adding to the knowledge on patient and public involvement: reflections from an experience of co-research with carers of people with dementia. *Health Expect* 2020; 23: 691–706.

Received 5 January 2023; editorial decision 5 July 2023