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Extended Research Article

Promoting activity, independence and stability in early dementia and mild cognitive impairment: the PrAISED research programme including an RCT

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Scientific summary

Promoting activity, independence and stability in early dementia and mild cognitive impairment: the PrAISED research programme including an RCT

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Scientific summary

Background

The prevalence of dementia is increasing with the ageing population and is expected to double in the next 30 years. About 950,000 people live with dementia in the UK. Dementia causes progressive deterioration in a person's cognitive and functional abilities. People with dementia are often dependent on other people. Dementia results in high levels of demand on health and social care as well as family and other informal carers. We need therapeutic interventions to reduce the decline in functional abilities so people with dementia can remain independent for longer. Exercise-based activities and functional rehabilitation may improve people with dementia's activities of daily living (ADL).

Objectives

The Promoting Activity, Independence and Stability in Early Dementia and mild cognitive impairment (PrAISED) programme aimed to develop and evaluate an exercise and activity intervention to increase independence in ADL for older people living with dementia or mild cognitive impairment (MCI). The programme comprised seven work packages (WPs):

WP1 – intervention development: develop, manualise and support the delivery of an evidence-based multicomponent therapy intervention.
WP2 – adherence and motivation: develop strategies to support engagement with the intervention and achieve long-term adherence.
WP3 – feasibility study: test the feasibility and practicality of delivering the intervention and conducting a randomised controlled trial (RCT).
WP4 – process evaluation: conduct process and realist evaluations of the trials.
WP5 – multicentre RCT: establish the clinical effectiveness of the PrAISED intervention in a multicentre RCT.
WP6 – health economics: establish the cost-effectiveness of the intervention and social return on investment (SROI).
WP7 – implementation: understand factors that would affect implementation of the intervention in practice.

Methods

Work package 1 – intervention development

The PrAISED intervention was developed by a team of clinical academics, practitioners and patient and public involvement and engagement representatives using evidence and theory from systematic reviews, interviews, focus groups, empirical studies and expert opinion. This followed work in an Alzheimer's Society PhD fellowship (Dr Vicky Booth) and a National Institute for Health and Care Research (NIHR) Programme Development Grant. We used theory about how to motivate people with dementia to do exercises. The intervention was described in a manual. We developed practitioner training courses. These were refined following experience in the feasibility study and described using the Template for Intervention Description and Replication (TIDieR) checklist.

Work package 2 – adherence and motivation

We initially used self-determination theory (SDT) to inform intervention development but later developed a new dementia-specific behaviour change model (PHYT-in-dementia), derived from literature reviews, synthesis and empirical evidence from the feasibility study. It was validated using interview data collected during the RCT process evaluation.

PHYT-in-dementia identified factors that mediate behaviour change and maintenance in people living with dementia. These were: characteristics of the person with dementia, support, expectations, goals, carer characteristics, progress, social opportunity, self-efficacy, capability, intervention characteristics, autonomy, control, physical infrastructure, personal history, information, knowledge, characteristics of therapists and personal beliefs.

Work package 3 – feasibility study

We conducted a three-arm randomised feasibility trial to establish that we could recruit and randomise participants at a sufficient rate, deliver the intervention in participants' homes across two sites, retain and follow up participants; that the intervention was practical and safe; that we could collect trial data and that our sample size assumptions were reasonable. We explored the level of supervision participants would need to undertake 3 hours of PrAISED exercises and activities a week and sustain this over the duration of the trial. We compared the PrAISED intervention with supervision over 12 months to a shorter intervention comprising nine therapy visits and three telephone calls delivered over 12 weeks and a control group who received a falls prevention assessment and advice. Data were collected at baseline and 12-month follow-up, during face-to-face interviews with two researchers. Health status measures comprised disability in ADL [Disability Assessment for Dementia scale (DAD)], habitual physical activity, quality of life (QoL), frailty, cognition, other intermediate outcomes and carer outcomes. Monthly calendars were completed for falls and activity ascertainment.

Work package 4 – process evaluation

We investigated implementation of the PrAISED intervention during the trials, the mechanisms of impact and context. We adopted a mixed-methods approach investigating fidelity, adaptations, dose and reach, including quantitative data, interviews and thematic analyses. Mechanisms of impact and context were identified through semistructured qualitative interview with a sample of therapists, participants and carers. Interviews were conducted 6 and 12 months into involvement in PrAISED. Interviews were conducted remotely during the COVID-19 lockdown between May 2020 and September 2020.

Work package 5 – multicentre randomised controlled trial

Participants were recruited from five sites in England via secondary care memory assessment clinics, general practice registers, dementia support groups and the NIHR Join Dementia Research register. Participants were recruited as patient–carer dyads.

The RCT was conducted between September 2018 and June 2022. This included the COVID-19 pandemic period, which impacted recruitment, intervention delivery and data collection. Between March 2020 and September 2020, research and intervention contacts were delivered remotely.

We included participants aged over 65 years, with a diagnosis of dementia or MCI, a Montreal Cognitive Assessment (MoCA) score of 13–25 (out of 30), a family member or unpaid carer who knew the participant well and who was willing to participate. Participants had to have mental capacity to consent and be willing to take part in an exercise intervention. Separate consent was taken for the carer.

Active intervention comprised a specially designed, dementia-specific, rehabilitation programme focusing on strength, balance, physical activity and performance of ADL, which was tailored, progressive and addressed risk, providing up to 50 therapy sessions over 12 months. The control group received usual care plus a falls risk assessment.

The primary outcome was ADL, measured at 12 months by the informant-completed DAD scale. Secondary outcomes included self-assessed ADL (Nottingham Extended ADL scale); cognition (MoCA, animal-naming verbal fluency; Cambridge Neuropsychological Test Automated Battery), balance (Berg Balance Scale); mobility and ability in divided attention [Timed Up and Go (TUG), dual-task (TUG)]; hand grip strength; health and social care resource use for patient and carer Client Service Receipt Inventory; fear of falling; frailty, mood; carer strain, carer and self-assessed health-related quality of life (EQ5D DemQoL scales), physical activity; step count by accelerometer; and apathy.

Participants were followed up after 12 months. Between months 1 and 15, self-completed calendars were used to record falls and PrAISED exercise undertaken. A brief postal follow-up questionnaire was completed by the patient's carer/informant after 6 months.

A sample of 368 participants (184 per group), with 23% attrition, had 80% statistical power to detect a change in disability outcome (DAD), with a moderate effect size of 0.5.

A secure internet-based system based in a Clinical Trials Unit was used to randomise individuals, 1 : 1, stratified by site, presence of a co-resident and history of previous falls.

Blinding of participants and therapists was not possible due to the nature of the intervention. Analysis was conducted blind.

An analysis of covariance was conducted for the primary outcome (DAD) at the 12-month follow-up, using group, stratification variables and baseline DAD score as covariates. The analysis was conducted on an intention-to-treat basis. Scaled secondary outcome measures were analysed similarly. Adjusted mean differences, *Cohen's d* standardised effect size, 95% confidence intervals (CIs) and *p*-values were reported.

Work package 6 – health economics

Cost–utility analysis using a Markov-modelled projection over a 15-year time frame, and a SROI analysis.

Work package 7 – implementation

We undertook four small-scale implementation studies, using the Consolidated Framework for Implementation Research. We investigated adaptation and adoption of a pilot service in routine practice at one site. We interviewed therapists who delivered the PrAISED intervention, commissioners and service leaders. We explored lack of participation by ethnic minority populations through discussions with community groups and leaders. We developed advice on compiling a business case for commissioning the intervention.

Results

We developed and refined the PrAISED intervention. This comprised a 12-month, home-based, individually tailored rehabilitation programme, focusing on strength, balance, physical activity and performance of ADL. Tailoring took account of individual history, personality and abilities, problems, interests, family and other resources. Fourteen core principles were defined to guide intervention delivery. A logic model was developed. Delivery was by physiotherapists, occupational therapists and rehabilitation support workers. Participants were encouraged to undertake a total of at least 180 minutes of exercise per week. The programme was progressed by therapists following periodic reassessments. Supervised sessions were tapered over the 12 months (twice-weekly visits in the first 3 months, reducing to monthly in the final 3 months) and community activities were signposted. An intervention manual was published. Therapists were supported throughout the intervention delivery period with training and regular clinical support sessions.

We reviewed behaviour change frameworks for older people and people living with dementia. We adapted SDT to support the intervention, which posits the importance of autonomy, relatedness and competence, and 12 practical support approaches. Further reviews led to the development of a new behaviour change framework, PHYT-in-dementia, which was adapted, validated and applied to the intervention for the multicentre RCT.

We undertook a two-site, three-arm feasibility RCT. We successfully recruited 60 participants, of whom 45 completed the intervention and provided outcome data. There were no serious, related adverse events (AEs). Missing data rates were satisfactory, apart from some scales that were investigating SDT. We made some other minor adjustments to eligibility criteria and outcome scales. We found that participants were unable to adhere to the programme in the absence of supervision and carried forward higher-intensity supervision but developed an algorithm to plan and gradually reduce intensity, considering ability to undertake activities independently. Analysis of outcomes supported the superiority of the higher-intensity programme and suggested moderate to large benefits in balance, gait speed and disability.

We undertook a five-site, two-arm RCT, powered to detect a moderate effect size on the DAD scale. We recruited 365 participants, median age 80 years, 42% female, median MoCA score 20/30, predominantly from less-deprived localities.

There were no significant differences in characteristics between groups at baseline. A median of 31 therapy sessions were delivered, interquartile range 22–40, 68% face to face. Fidelity judged from (pre pandemic) video-recorded therapy sessions was good. Intervention group participants reported undertaking an additional mean of 121 minutes of exercise per week. Two hundred and ninety (79%) were followed up. There were no significant differences on the primary outcome, the DAD: adjusted mean difference −1.3 (95% CI −5.2 to 2.6); standardised effect size (*d*) −0.06, 95% CI −0.26 to 0.15; $p = 0.5$; or on physical activity, balance, QoL, cognition or a range of other measures. There was a statistically significant small difference in favour of the control group, on the dual-task TUG test and on the self-report DemQoL scale. Upper 95% CIs excluded even small benefits on other scales. Rate of falling was reduced by 22%, but this was not statistically significant. Results did not change in a range of sensitivity analyses. Both service delivery and research were disrupted by the COVID-19 pandemic. Recruitment was delayed, some follow-up was undertaken remotely and some intervention sessions were delivered by telephone or video call, which were consequently much less ambitious than intended. Community facilities and activities became unavailable to vulnerable people. Results were no different for those completing the intervention before the COVID-19 pandemic.

One hundred and sixty-seven AEs were recorded: 59 in control and 108 in the intervention groups, involving 68 participants. There were 91 serious adverse events: 29 in control and 62 in intervention, involving 60 participants. None was serious and related to intervention. There was no statistically significant difference between the intervention and control groups for AEs.

The process evaluation studied implementation of the intervention, mechanisms of impact and context. Eighty-eight interviews were undertaken with participants, carers and staff. The PrAISED intervention was well received among participants and clinicians. Many gave examples of benefits gained as a result of taking part in PrAISED. However, cognitive impairment, physical comorbidity and fear of falls or getting lost prevented independent engagement. Tapered support was ineffective and acted as a barrier to continued engagement. Family members played a major role in supporting participation. A realist evaluation considered mechanisms behind the social benefits and concluded that participants improved social interactions when therapy activities were tailored to their preferences, when therapy support was maintained and when participants perceived improvements as a result of the intervention.

The cost-effectiveness study showed a cost/quality-adjusted life-year of £130,000. SROI suggested benefits, but only in the feasibility and pre-COVID phases of the study. Participants completing the trial after the start of the pandemic had a negative social return, predominantly due to lack of availability of community facilities.

We introduced PrAISED into routine practice in a socioeconomically deprived part of Nottingham. Eleven participants were referred and completed a shorter version of PrAISED, less than half what was anticipated or provided for. The intervention was well received by those who participated. We investigated reasons behind poor recruitment of participants from ethnic minority groups, finding feelings of mistrust towards health services and research, and stigma against dementia. We interviewed commissioners to provide guidelines on constructing a business case for implementing exercise and post-diagnostic support programmes.

Conclusions

We delivered an ambitious programme of research to address whether we can intervene to maintain safe activity and independence after a diagnosis of dementia. We systematically designed a new dementia-specific intervention, and used multiple methods to evaluate it, centred around a multicentre RCT. The intervention was about as intensive as it would be possible to deliver in the UK health and cultural context. Despite positive reception and perceived benefits by participants, we measured no benefits from the programme. Our RCT was significantly disrupted by the COVID-19 pandemic. This, a lack of diversity in the participant population and the fact that the outcome measures used might not have captured the impact of the intervention, leave persisting uncertainties about whether a PrAISED-like intervention might be beneficial. However, our findings suggest that a more ‘supportive’ approach to health care after a diagnosis of dementia may be appropriate, helping to manage problems associated with inevitable functional decline, rather than trying to change the course of disease or to maintain abilities. This would involve developing therapeutic relationships, providing support to live with limitations, minimising intervention burden, maintaining personhood, inclusion and occupation, providing psychological and emotional support and support to family and other carers.

Study registration

This study is registered as ISRCTN10550694, 15320670.

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