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Programme Grants for Applied Research

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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This article

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Abstract

Background: Dementia represents a major public health challenge worldwide. Interventions are required to maintain functional ability and prevent crises. Exercise-based therapy may improve activities of daily living and prevent falls.

Objective: We aimed to systematically develop an intervention, called Promoting Activity, Independence and Stability in Early Dementia and mild cognitive impairment (PrAISED), and evaluate its clinical and cost-effectiveness.

Design: A mixed-methods study.

1. Literature review, co-design, patient and public involvement and practical experience were used to develop and refine a therapy intervention. We applied principles of behaviour change to promote engagement and motivation.
2. Three-arm feasibility randomised controlled trial to test research procedures, the practicality of intervention, and establish the need for prolonged supervision.
3. Two-arm, multicentre randomised controlled trial, comparing intervention with control, with 15 months' follow-up.
4. Process and realist evaluations, including quantitative data, interviews and thematic analyses.
5. Health economic evaluations, including a cost-effectiveness analysis using Markov modelling and social return on investment.
6. Implementation study.

Setting: Therapy and research were undertaken in participants' homes and local communities across 5 sites in England.

Participants: People with diagnosed mild dementia or mild cognitive impairment, Montreal Cognitive Assessment score 13–25, living at home and a family member or carer. In the main trial, there were five sites in England, participants were 98% White ethnicity and 20% had mild cognitive impairment.

Interventions: A specially designed, dementia-specific, rehabilitation programme focusing on strength, balance, physical activity and performance of activities of daily living, 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.

Main outcome measures: The primary trial outcome was the informant-reported Disability Assessment for Dementia 12 months after randomisation. Secondary outcomes were: self-reported activities of daily living, physical activity, quality of life, frailty, balance, functional mobility, cognition, fear of falling, mood, carer strain and service use (at 12 months) and falls (between months 4 and 15).

Results: Three hundred and sixty-five people were randomised in the multicentre trial, 183 to intervention and 182 to control. Median age of participants was 80 years (range 65–95), median Montreal Cognitive Assessment score was 20/30 (range 13–26) and 58% were men. Participants received a median of 31 (interquartile range = 22–40) therapy sessions out of a possible maximum of 50. Participants reported completing a mean 121 minutes/week of PrAISED activity. Primary outcome data were available for 149 (intervention) and 141 (control) participants. There was no difference in Disability Assessment for Dementia scores between groups: adjusted mean difference −1.3/100, 95% confidence interval (−5.2 to 2.6); *Cohen's d* effect size −0.06 (−0.26 to 0.15); $p = 0.5$. Upper 95% confidence intervals excluded small to moderate effects on any secondary outcome measures. Between months 4 and 15, there were 79 falls in the intervention group and 200 falls in the control group, and adjusted incidence rate ratio was 0.78 (0.5 to 1.3); $p = 0.3$.

Participants and therapists liked the intervention and thought that it produced health benefits. Tailoring, perceiving benefits, professional supervision and family or carer support were important facilitators. Cognitive and physical impairment, risk aversion and tapering the level of support were barriers. Therapeutic relationship between participant and therapist was important.

The cost per quality-adjusted life-year gained was £130,000 over a lifetime horizon. Social return on investment was positive before the onset of the COVID-19 pandemic but was negative after the first pandemic lockdown, largely due to unavailability of access to community facilities.

Limitations: The multicentre randomised controlled trial was disrupted by the COVID-19 pandemic. The first lockdown occurred when 301 participants had been randomised and 64 participants had completed the trial. Recruitment was suspended, and some therapy and data collection were undertaken remotely. The intervention was diminished compared with in-person delivery, but reported fidelity remained reasonable. Our participant population lacked socioeconomic and ethnic diversity – over 30% lived in the least deprived decile of postcodes. The intervention was very popular with participants and therapists, and it is possible that our predominantly biomedical and functionally orientated outcome variables failed to capture intervention benefits.

Conclusions: The intensive PrAISED programme of exercise and functional activity training did not improve activities of daily living, physical activity, quality of life, reduce falls or improve any other secondary health status outcomes. Due to the pandemic, the population recruited, and the outcomes chosen, some uncertainty remains about the effectiveness of the intervention.

Future work: Consider: (1) repeating the trial outside of a pandemic; (2) more psychosocial outcomes, such as social participation, affirming personhood and valuing therapeutic relationships; (3) alternative approaches to risk reduction and ability maintenance in dementia; (4) other models of support to manage problems associated with inevitable progression and decline; (5) that conventional randomised controlled trials may not be the best way to evaluate complex intervention for complex and degenerative conditions; interpretative and realist methods should supplement evaluation; and (6) work to include a wider range of ethnicities and socioeconomic circumstances.

Study registration: This study is registered as ISRCTN10550694, 15320670.

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Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/PLNV0118).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

ADL	activities of daily living
AE	adverse event
AES	Apathy Evaluation Scale
ANCOVA	analysis of covariance
CANTAB	Cambridge Neuropsychological Test Automated Battery
CEA	cost-effectiveness analysis
CFIR	Consolidated Framework for Implementation Research
CMOc	context–mechanism–outcome configurations
CONSORT	Consolidated Standards of Reporting Trials
CSI	Carer Strain Index
CSRI	Client Service Receipt Inventory
CTU	Clinical Trials Unit
DAD	Disability Assessment for Dementia
DemQoL	dementia quality of life
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practitioner
FES-I	Falls Efficacy Scale – International
FINALEX	Finnish Alzheimer Disease Exercise Trial
HADS	Hospital Anxiety and Depression Scale
HCP	healthcare professional
ICER	incremental cost-effectiveness ratio
IMD	Index of Multiple Deprivation
JDR	Join Dementia Research
LAPAQ	Longitudinal Study of Ageing Amsterdam Physical Activity Questionnaire
MAS	Memory Assessment Services
MCI	mild cognitive impairment
MoCA	Montreal Cognitive Assessment
MRC	Medical Research Council
NEADL	Nottingham Extended Activities of Daily Living
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
PPIE	patient and public involvement and engagement
PrAISED	Promoting Activity Independence and Stability in Early Dementia
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial
REC	Research Ethics Committee
RSW	rehabilitation support worker
SAE	serious adverse event
SDT	self-determination theory
SHARE	Study of Health, Ageing and Retirement in Europe
SROI	social return on investment
TUG	Timed Up and Go
UC	usual care
WP	work package

Plain language summary

Dementia causes deterioration in memory and thinking abilities. The Promoting Activity, Independence and Stability in Early Dementia (PrAISED) programme aimed to develop and test a physical exercise and activity intervention to improve the ability to do daily activities among older people in the early stages of dementia.

We developed a therapy programme specifically designed for people with dementia. We paid particular attention to encouraging participation. Therapy was tailored to participants' goals, preferences and abilities. We confirmed that we could deliver the intervention and do the research to test it in a small-scale feasibility study.

We tested PrAISED by recruiting 365 people with dementia and a family member from five English counties. We randomly assigned them to receive PrAISED therapy or to a control group, who were given advice on falls prevention. The PrAISED group received up to 50 therapy sessions, delivered by trained therapists, and were also encouraged to do exercises on their own. At the start and after 12 months, we measured ability to do everyday activities and other aspects of health, including falls, quality of life, activity and National Health Service and social care use. We did interviews and observations to explain the findings.

Those receiving PrAISED therapy did no better on any of our measurements than those in the control group. The therapy programme was popular, and participants described benefits to their lives. Professional supervision and family support were important. However, memory and physical health problems often prevented full participation. The study was disrupted by the COVID-19 pandemic.

An economic study showed that PrAISED was not cost-effective. A method which values social outcomes suggested that PrAISED gave a good return before the pandemic but not during it.

We conclude that it might be more appropriate to help people manage problems associated with the inevitable decline seen in dementia rather than to try to change the course of the disease.

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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Synopsis

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Introduction and background

Some definitions

Dementia is a neurological syndrome causing loss of memory and other cognitive abilities. Dementia is progressive, irreversible and interferes with activities of daily living (ADL).[2] Mild cognitive impairment (MCI) is a measurable loss of mental function, which does not interfere with ADL but shares some features with dementia and often precedes future deterioration.[3]

Disability is the inability to carry out tasks and activities that a person needs or wants to do.[4] There are multiple possible types of disability, including mobility, ADL (personal, domestic and leisure tasks), continence and behaviours. Dependency is the need for human help to manage personal maintenance, ADL or safety. A fall is when someone unintentionally comes to rest on the ground, with or without loss of consciousness or overwhelming force.[5]

The problem with dementia

Dementia constitutes one of the most pressing public health issues of modern times. Its consequences are devastating for individuals and their families and contribute to ever-increasing demands on acute hospitals, community health, social services and institutional care.[6]

The prevalence of dementia rises exponentially with age, from about 1% of people aged 65, to 20% at age 80, and 30–40% at age 90.[7,8] There are 950,000 people with dementia in the UK, increasing to 2 million by 2051, due to ongoing demographic change.[9] Dementia has motor as well as cognitive manifestations, including impaired gait and balance. Dementia can affect ADL through problems with memory, agnosia, apraxia, planning, sequencing or apathy. People living with dementia often have physical comorbidities, sometimes multiple, which are themselves disabling. In addition, opportunities to be active may be restricted, because of social isolation, stigma, concerns about falls, getting lost or accidents, lack of available human assistance or the environment and public facilities not being adapted for the needs of people with dementia. People living with dementia are more prone to acute illness, injury, delirium, acute hospital admission and poor functional recovery afterwards. Dementia is a major reason for care home admission; one in three people with dementia lives in a care home.

People living with dementia are often dependent on family members or other people. Carers are often spouses or partners, who may be old and frail themselves, adult children or grandchildren, or a range of others, such as siblings, nephews and nieces, neighbours or friends. Caring is costly, in terms of time, physical and emotional strain, and is associated with poorer health. Family or so-called 'informal' caring is often supplemented by professional health and social care.

People with cognitive impairment are at high risk of falling, even at the earliest stages, with a twofold risk compared with cognitively intact older people. Each year, 60–80% of people with dementia fall.[10–13] Falls lead to adverse health outcomes, including injury, fractures, loss of confidence, accelerated decline in physical and mental function and carer strain. There are 75,000 hip fractures annually in the UK and 200,000 other fragility fractures. About 40% of hip fractures occur in someone with dementia.[14]

Outcomes of healthcare intervention in dementia

Policy advocates 'living well' with dementia.[15] Many people living with dementia are very old, and approaching the ends of their lives, so reducing mortality is not a key goal. Quality of life is important, but strictly defined, in terms of a personal valuation of a state of health, is very difficult to determine for a person living with dementia. A variety of questionnaire-based scales have been developed, including some specific for dementia, based on ascertainment of levels of functioning and expression of emotion or distress.[16] Quality of life is affected by many factors other than health status and can be poorly sensitive to changes arising from healthcare interventions.

The primary goal of rehabilitation therapy is optimisation of function, so measures of mobility and ADL are often used as generic global outcome measures. There are many validated scales. In the context of a progressive disease, ADL is likely to decline over time.

Activity extends beyond ADL to include physical exercise and social engagement. As exercise is generally beneficial, this can be measured as an outcome, either via questionnaires or directly using accelerometers. Defining duration and intensity of activity on a self-report basis is approximate and may be invalid for a person living with dementia.

Independence is related to ADL performance and safety awareness, but it is an ambiguous concept, as we are all interdependent. Some frameworks for measuring independence exist.[17] Both independence and ADL attribute the outcome to the individual with dementia, whereas in dementia, account should also be taken of supported performance of tasks, impact on carer or carer-network well-being, or the health of the relationship between the individual with dementia and the carer.

Broader outcomes include well-being, inclusion, occupation and person-centredness, which could be argued to be the primary goal of care, but all of which are difficult to operationalise.[18]

Rationale for a research programme

Current policy aims to diagnose dementia early, and provide support which might avoid or delay crises, disability and dependency. However, current services may be inadequate to achieve this. In 2014, the NHS Five Year Forward View argued that 'the sustainability of the National Health Service (NHS) … depends on a radical upgrade in prevention … Derek Wanless' 2002 health review warned that unless the country took prevention seriously, we would face a sharply rising burden of avoidable illness. That warning was not heeded – and the NHS is on the hook for the consequences'.[19]

An approach that could plausibly deliver benefits, at sufficient scale, is to intervene when early signs of impending loss of function become evident. Early intervention may increase baseline resilience, slow disease progression, mitigate negative effects, prevent crises or complications, so critical thresholds for disability are delayed, at a time when the individual has capacity to learn and sustain lifestyle changes. Measures to promote activity and prevent falls in early dementia fit this model.

Frailty is the propensity to crises and adverse health outcomes, caused by loss of physiological reserve, or accumulation of deficits across multiple organ systems.[20] Many people with dementia are frail, but in addition, dementia itself can be seen as a cause of frailty, conferring a vulnerability to crises and functional decline. Responses to frailty include undertaking comprehensive geriatric assessment and attempts at reversal through physical exercise and high-protein nutrition.

In clinical practice, physiotherapists and occupational therapists use pragmatic, task-centred activities to help patients overcome the functional consequences of ill health, by retraining lost functions (restoration), finding ways of using residual functions to complete tasks successfully (adaptation), or using aids and appliances to assist in task performance.

Falls prevention in older people has been extensively researched. Risk factors are muscle weakness, neurological disease, medications, poor vision and environmental hazards. Strength and balance exercises and multifactorial interventions reduce risk,[21,22] but these interventions have not been shown to reduce falls in people with dementia or MCI.[23–25] Falls guidelines recommend that cognitive function is assessed, but do not say how to respond.[22,26] A systematic review of falls prevention interventions concluded that recommendations were poorly adapted to the needs of people with dementia.[27]

People with dementia have more conventional falls risk factors than people of a similar age without dementia.[28,29] They also have dementia-specific risk factors, including type and severity of dementia, cognitive and gait impairments, behavioural disturbances and psychotropic medication use.[13,29–31] Studies highlight the importance of attention, and dual-task cost (increased risk when concentrating on two things at once),[32,33] manifestations of impaired executive function (ability to form, maintain and shift mental set).[34] Abnormalities in executive function and gait predict falls.[35–37] Dual-task and gait abnormalities are found early in Alzheimer's disease[13,38–40] and MCI.[41]

Potentially reversible risk factors provide opportunities to intervene before inevitable deterioration occurs. Systematic reviews have considered strength and balance training in older people, with and without dementia.[25,42–46] Moderate-intensity exercise, two to three times a week, improves strength and gait speed.[47–51] Exercise may slow cognitive decline,[47,50,52,53] although the size of this effect appears small, at best. There was insufficient evidence to confirm reduction in falls, improved ability in ADL, mood, behaviour or carer strain for people with dementia.[25,27,46,47,49,50] Training, including resistance exercise, can improve executive function, dual-task performance and gait parameters,[54–59] requiring about the same intensity as falls prevention exercises. Functionally orientated therapy can improve ability in ADL.[60,61] In general, however, the quality of evidence was poor; most trials were small and at high risk of bias. Customary levels of physical activity are low among older people.[62]

A high-quality Finnish trial [Finnish Alzheimer Disease Exercise Trial (FINALEX)] of 12 months of twice-weekly, supervised exercise at home for people with established dementia and their co-resident spouse, slowed the rate of functional loss and halved the rate of falling.[63] The FINALEX study intervention cost £5000 per couple but halved hospital admissions and accrued overall savings of £6000 over 2 years. This demonstrated that intensive exercise is achievable, sustainable with the right support, and cost-effective. The challenge is how to achieve sufficient participation, adherence and persistence in the NHS and British cultural environment, and to be inclusive, for example, of the 50% of people with early dementia who live alone. Small Australian trials have successfully demonstrated the feasibility of falls prevention trials in dementia.[64–66] Development and evaluation of interventions that combine motor and cognitive rehabilitation have been repeatedly suggested.[28,37,61,67] Gait training helps mobility in patients with Parkinson's disease.[68,69]

A new intervention would have to produce changes in individuals that were physiologically and neuropsychologically credible, but also take account of the need for behaviour change.[70–73] Interventions need to overcome barriers to engagement and uptake, including unwillingness to be thought of as being incapable or at risk of falls,[74,75] spending time and effort for future benefit, and to facilitate long-term adherence. The utility of existing frameworks (e.g. behaviour change wheel[70]) in the context of dementia is unknown but provide a basis for further investigation.

Change in health policy requires demonstration of both clinical and cost-effectiveness, to enable comparison between competing demands on resources. Interventions in a progressive condition towards the end of life raise epistemological challenges, including defining appropriate outcomes and outputs. We planned to evaluate cost-effectiveness within the short term of a trial, across the 5–10-year life expectancy of participants, and using a social return on investment (SROI) analysis, a method which identifies and monetises a range of benefits to key stakeholders, as anticipated benefits will not be limited to the NHS.[76,77]

Programme aims and objectives

Aim

To develop and evaluate an intervention to maintain activity and independence and prevent falls for people living with mild dementia and MCI, called Promoting Activity Independence and Stability in Early Dementia (PrAISED).

Research objectives

1. To develop a practical and acceptable intervention.
2. To determine how to support engagement and uptake of the intervention and achieve long-term adherence.

3. In a feasibility study, to determine:
    a. If the intervention could be delivered in practice.
    b. How much supervision was required for successful delivery.
    c. If trial assumptions were correct, and procedures and data collection were feasible.

4. In a multicentre randomised controlled trial (RCT), to determine the clinical effectiveness of the intervention in terms of disability, falls, activity, QoL, cognition and carer impact.
5. In process and realist evaluations, to determine:
    a. Whether the intervention was delivered as intended, the mechanisms for any effect, and facilitators and barriers to implementation.
    b. Social outcomes affected by the intervention and subgroups who might benefit differently.

6. To determine the cost-effectiveness and SROI of the intervention.
7. To answer implementation questions:
    a. Could a pilot service be implemented in routine practice?
    b. How to maximise equitable access to the service?
    c. To develop a business case to enable the service to be commissioned.

Alterations to the programme

We undertook a feasibility study to test the PrAISED intervention and research methods and made minor changes to inclusion criteria and some of the health status measurement scales used. To facilitate recruitment, we extended the permissible range on the baseline Montreal Cognitive Assessment (MoCA) from 15–25 to 13–25 and introduced recruitment from general practitioner (GP) dementia registers. We added a brief QoL and service-use questionnaire 6 months after randomisation. The process evaluation was extended to include a realist evaluation of social outcomes. Four PhD studies were linked to the programme: on apathy in dementia, therapists' training, a dementia-friendly exercise class and a functional magnetic resonance imaging (MRI) study.

The COVID-19 pandemic disrupted the programme. We suspended recruitment and face-to-face contact on 17 March 2020, when we had recruited 301/368 participants to the RCT. The research data set was immediately revised, to omit elements that required physical presence. Research data were collected by post, telephone or video call. A protocol for remote therapy delivery, via telephone or video call, was developed. Participants who had been taking part for at least 3 months had an additional interim data collection point instituted in case the trial had to be abandoned, and no further data collected.

Sample size estimates were re-examined under a range of feasible pandemic impacts. Recruitment was restarted from 1 October 2020, with a further pause during the second lockdown in December 2020–January 2021. Face-to-face therapy and trial data collection were restarted, where this was acceptable to participants, using personal protective equipment, although some remote therapy and data collection continued. Recruitment was extended by a year and finished on 30 June 2021. The Oxford site was unable to restart recruitment. Follow-up was completed in October 2022. Statistical and economic evaluations investigated potential measurable pandemic impacts. The process evaluation was extended to investigate the pandemic experiences of participants and therapists and the implementation of remote therapy. The MRI study was abandoned, as scans required attendance at the hospital site.

In November 2021, National Institute for Health and Care Research (NIHR) awarded us funds to undertake a 'bolt-on' implementation study. This comprised:

- Introducing a 6-month-duration pilot service in one socioeconomically deprived locality (Nottingham).
- Undertaking an implementation analysis using the Consolidated Framework for Implementation Research (CFIR).[78,79]
- Exploring barriers and facilitators to the inclusion of ethnic minority participants in the service and research.
- Developing a business case for commissioning the service.

Work package summaries

The programme comprised seven interlinked work packages (WPs).

Work package 1: intervention development

Preliminary qualitative work: https://doi.org/10.1371/journal.pone.0177530; https://doi.org/10.1136/bmjopen-2018-025702

Literature reviews: https://doi.org/10.12968/ijtr.2015.22.6.289; https://doi.org/10.1136/bmjopen-2018-024982; https://doi.org/10.1186/s13643-016-0212-x; https://doi.org/10.1016/j.jshs.2020.06.003

Intervention development: https://doi.org/10.1177/0269215518758149

The aim was to develop, manualise and support delivery of an evidence-based multicomponent therapy intervention.

The intervention was developed using the Medical Research Council (MRC) guidelines for complex interventions.[80] A structured approach considered theory, evidence and practical experience from 15 data sources, including: literature reviews, clinician workshops, expert opinion meetings, patient-relative interviews, and focus groups with people living with dementia, their carers and clinicians.[81,82] Data were synthesised, manualised and tested through an initial proof-of-concept study[83] and the feasibility study (WP3).[84] Learning from the feasibility study helped refine the intervention using feedback from participants, carers and therapists and patient and public involvement and engagement (PPIE) groups. These refinements included clarification on what the PrAISED intervention comprised, psychological theory to support adherence and a decision tree to aid clinician's decisions on the intensity of the intervention.

The finalised intervention was described using the Template for Intervention Description and Replication (TIDieR) checklist[85] (*Report Supplementary Material 1*) and manualised for use in the randomised controlled multisite trial (RCT) in WP5. The manual is available in *Report Supplementary Material 2*.[86]

To support fidelity of intervention delivery across the five sites in the RCT, a programme of clinician training and mentoring was developed. This comprised a 2-day training workshop using case studies from the feasibility trial, experiential learning, action learning and adult learning theories. On-site group mentoring sessions (up to two per site) and monthly peer-mentoring was implemented to support problem-solving and adaptation of the intervention. A refresher workshop was provided halfway through the intervention delivery period.

The PrAISED training programme was designed, refined and evaluated using a realist evaluation, and identified four key components (Louise Howe, PhD; https://eprints.nottingham.ac.uk/78043/ (*Figure 1*):

1. Motivational strategies that established and sustained habitual routines.
2. Progressive physical exercises to improve and maintain strength and balance.
3. Functional activity training to develop an individual's independence in ADL.
4. Plans to maintain activities and exercises, through signposting community facilities.

Fourteen principles underpinned these four key components:

1. Intensive exercise (180 minutes of physical activity per week).
2. Tailored physical activity.
3. Tasks must be challenging.
4. Task difficulty must be progressive.
5. Tasks must promote or improve independence.
6. Supporting ADL.
7. Supporting dual-tasking.
8. Accessing the environment.
9. Embracing positive risk-taking.
10. Using motivational theories.
11. Assisting in habit formation.
12. Using tapering to promote self-management.
13. Promoting long-term engagement.
14. Participant-specific goal-setting.

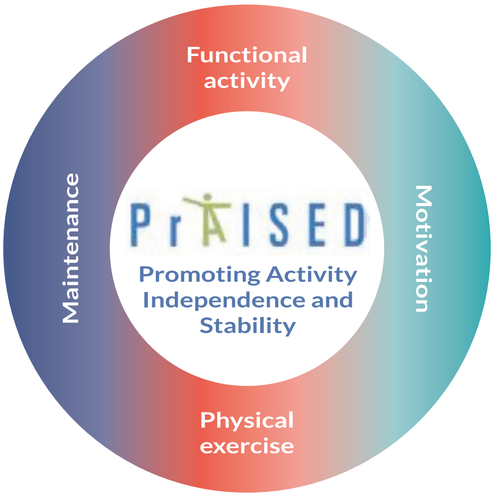

FIGURE 1 The PrAISED intervention with core components.

Registered allied health professionals made initial assessments and set goals, designed the individualised programme, reassessed and progressed it as appropriate, and reviewed and managed problems. Rehabilitation support workers (RSWs) supervised engagement with the programme and encouraged exercise and activity between supervised sessions.

Sixty-three clinicians (23 occupational therapists, 18 physiotherapists and 22 RSWs) completed initial training during 21 sessions over 28 months from September 2018 to January 2021. Four initial training workshops were undertaken virtually due to the COVID-19 pandemic. There were 8 on-site mentoring sessions (2 were virtual) and 42 monthly virtual mentoring sessions, with a mean of 6 clinicians attending per session. A refresher training conference was held in February 2020. More training was required than expected due to a high turnover of staff.

Previous clinical experience of staff participants working with people with dementia varied. The structure of the training programme allowed for differing training needs to be addressed. Training focused on the PrAISED core principles and used clinical vignettes, which allowed therapists to develop their skills and knowledge.

Three limitations were identified:

1. The training programme (for staff participants) and the intervention programme (patient participants) had to be adapted during the COVID-19 pandemic. They were originally designed to be delivered face-to-face but had to be adapted to virtual delivery. Although the same content was delivered with a consistent approach and support, opportunities for physical activity and progression were restricted, especially those outside the home.
2. There was a high turnover of intervention delivery staff during the RCT. Staff participants were frequently recruited from NHS organisations and had conflicting clinical and research roles.
3. Frequent changes to staffing structures and roles necessitated more training, often in smaller groups, resulting in fewer opportunities for peer-to-peer learning. This was mitigated by discussions with the trainers (Louise Howe, Vicky Booth, Alison Cowley), who were registered physiotherapists and occupational therapists with clinical and academic expertise in dementia.

Work package 1 demonstrated that an evidence-based intervention could be developed and manualised, that NHS therapists could be trained to deliver it, and through testing in both the feasibility study and RCT that people with dementia adhered to it.

The PrAISED intervention programme was designed to be delivered 1 : 1 at home. However, it was acknowledged that there was potential for group exercise interventions, and an additional study developing a dementia-friendly exercise class was implemented in 2018 and evaluated in 2019[87] (Annabelle Long PhD https://eprints.nottingham.ac.uk/74166/).

Work package 2: adherence and motivation

Adherence: https://doi.org/10.1016/j.pmedr.2017.05.007; https://doi.org/10.1080/13607863.2019.1590308; https://doi.org/10.1016/j.pmedr.2020.101139

Motivation: https://doi.org/10.1136/bmjopen-2018-024982; https://doi.org/10.1093/ageing/afad031

Self determination theory: https://doi.org/10.1371/journal.pone.0217387

PHYT-in-dementia: https://doi.org/10.1016/j.maturitas.2019.01.008; https://doi.org/10.3390/ijerph17051544

The aim was to develop strategies to support engagement, to overcome barriers and to achieve long-term adherence to the PrAISED intervention.

Using theory to inform intervention design and test effectiveness can help identify not just what works but how it works, the underlying causal mechanisms. The approach was a dynamic, pragmatic and iterative process involving understanding problems, stakeholder involvement, and drawing on theories and evidence.[88]

Initial literature reviews were undertaken:

1. A systematic review of adherence support strategies in exercise interventions for people with MCI and dementia.[89] Findings suggested multiple strategies that may be helpful (individual tailoring, goal-setting, telephone calls or reminders, individual supervision, music). Lack of high-quality evidence limited firm conclusions.
2. A realist review to extend the range of data on supporting exercise engagement in people with dementia,[90] which identified 'perceived benefit' and 'support from a therapist or carer' as key motivators.

Literature suggested parallels between person-centred approaches in dementia and SDT,[91] which was used to inform the initial PrAISED intervention. According to SDT, individuals are more likely to persist in an activity when their basic psychological needs of autonomy, competence and relatedness are met. In the context of exercise for older adults with cognitive impairment, these needs could be satisfied by creating an environment that supports their autonomy in choosing activities they enjoy, building their competence through tailored exercise and fostering social connections through positive interactions with clinicians and carers. It was theorised that by meeting these needs, the likelihood of older adults with cognitive impairment engaging in the exercise and activities would increase. SDT can be a useful framework for enhancing exercise motivation, but it had not been tested in this population.[92,93] The broad principles of SDT informed intervention content (a goal-setting interest checklist) and the interpersonal style of delivery (needs-supportive communication strategies). Clinicians received face-to-face SDT-based training on how to motivate participants and were provided with a detailed description of 12 strategies designed to satisfy individuals' basic psychological needs (e.g. taking time to understand the participant, acknowledging the participant's feelings, providing rationale).

An interview study explored barriers and facilitators influencing adherence to the intervention during the feasibility study (WP3). Twenty participants were interviewed at home 4 months after their first clinician visit. Participants were purposively recruited to obtain a balance of those in the different feasibility study trial arms and with high and low adherence. Findings revealed that development of an exercise routine, practical and emotional support, memory prompts, past experiences, purpose and belief in benefits were key factors for engagement.[94] Long-term adherence was explored through 12 participant case studies constructed from interview data (collected at 4 and 13 months) and self-reported adherence (up to 24 months after the programme). Provision of basic needs support over time, intrinsic motivation, and tailoring to the participants' needs and preferences over time were important for long-term adherence.[89,95–97]

Following the feasibility study and further literature review, we developed a new behaviour change framework specifically for dementia, PHYT-in-dementia.[98,99] The model was validated based on interview data (n = 20) collected as part of the process evaluation for the multicentre RCT (WP4).[100,101] Focus groups with stakeholders (individuals with cognitive impairment, carers and clinicians) corroborated the findings of the realist review.[97] Perceived benefits of exercise were described by participants to include enjoyment, remaining independent and keeping fit and healthy. Support from others (e.g. family and clinicians) was viewed as important for encouraging engagement and supporting confidence to do exercises (*Figure 2*).

Limitations: we intended a quantitative approach to investigating adherence, using scales to investigate underlying constructs, including the Basic Psychological Need Satisfaction and Frustration Scale,[102] Behavioural Regulation in Exercise Questionnaire-2[103] and the Habit Formation Index.[104] Results showed high rates of missing data (> 40%) for these scales, and feedback from participants and research assistants indicated that participants struggled with understanding. Therefore, we included questions around behaviour change in the qualitative interviews of the main trial process evaluation (WP4) and omitted the quantitative assessment of behaviour change.

Work package 3: feasibility study

Feasibility study protocol: https://doi.org/10.1186/s40814-018-0239-y

Feasibility study results: https://doi.org/10.1186/s12877-019-1379-5

The aim was to answer the question *'can this study be done?'* before investing in a costly definitive trial. We undertook a 2-site, 3-arm randomised feasibility trial comparing interventions providing 50 therapist visits delivered over 12 months (high-intensity supervision), 9 therapy visits and 3 phone calls delivered over 12 weeks (moderate-intensity supervision), and a control arm of brief falls prevention assessment and advice (*Table 1*).[105] The high-intensity supervision was tapered over time: visits were twice-weekly for 3 months, once-weekly for 3 months, once-fortnightly for 3 months and once a month for the final 3 months, aiming to promote independent undertaking of the exercise programme.

Research questions comprised:

1. Could participants be recruited and randomised at a sufficient rate? Participants were expected to complete 180 minutes of physical exercise and activities per week for a year. This expectation was emphasised, as a clear commitment to completing the study, and ability to participate for the duration was needed to make a trial feasible.

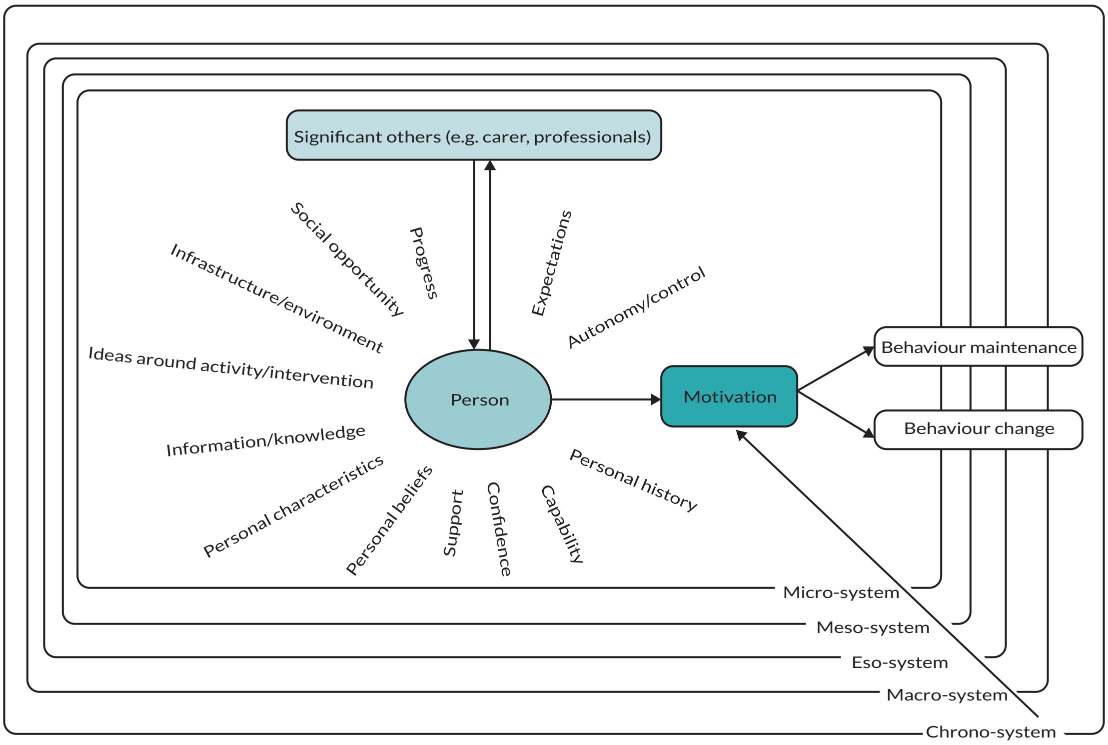

FIGURE 2 The revised PHYT-in-dementia behaviour change framework.

TABLE 1 Components of each intervention arm in the feasibility study

Intervention arm	Intervention components
High-intensity supervision	• Fifty, 60- to 90-minute visits from an occupational therapist, physiotherapist or RSW over 12 months (13 visits from a therapist, 37 from a RSW) • Therapists completed assessments and developed a personalised activity and exercise plan for the participant, tailored to their personal goals • The plan was reassessed and revised at regular intervals throughout the 12 months • RSWs supervised the participants doing the planned activities and exercises • Visits were tapered, with two visits/week for the first 3 months, one visit/week for months 4–6, one visit/fortnight for months 7–9 and one visit/month for months 10–12 • Therapists signposted the participant to community services so they could continue their exercises
Moderate-intensity supervision	• Nine visits from an occupational therapist or physiotherapist plus three telephone calls over a 13-week period • Initial visits assessed the participant and developed a personalised activity and exercise plan as for the high-intensity supervision intervention • Visits were tapered over the 3 months
Control	• One to three visits from an occupational therapist or physiotherapist for a falls prevention assessment and advice, depending on assessed need

2. Could the intervention be delivered across multiple sites and in participants' homes? It was necessary to establish whether staff could be trained to deliver the intervention in sites with different models for intervention delivery.
3. Could participants be retained? Concerns included that those in the control arm would withdraw before the final follow-up visit and that those in the two active arms would find requirements of the intervention too onerous.
4. What level of supervision intensity would be required? We needed to establish the optimum amount of supervision needed to sustain engagement and achieve sufficient exercise outside professionally supervised sessions. More therapy and supervision visits were more expensive to deliver, but fewer therapy visits over a shorter time may not be sufficient to establish an exercise habit. An active control was included at the request of NIHR to incentivise retention, although this was not an intervention that participants would have received routinely.
5. Were there any unexpected or adverse consequences? The intervention included exercise and activity advice consistent with that recommended by the World Health Organization. Nevertheless, it was important to ensure that the intervention did not have unexpected consequences.
6. Could blinded research data be collected without overburdening participants? Participants were older and had cognitive impairment. A lengthy interview could have been burdensome. We did not specify the necessity of recruiting a family carer to avoid excluding those without family. The impact of this on data collection had to be assessed.
7. Were sample size assumptions reasonable?

Participants were recruited through memory assessment service clinics and the Join Dementia Research (JDR) register. After mental capacity assessment, consent and collection of baseline data, they were randomised 1 : 1 : 1 via a secure web portal held at the NWORTH Clinical Trials Unit (CTU), Bangor University, managed by an independent statistician.

Participants were over 65 years, had a clinical diagnosis of mild dementia or MCI, were able to walk without human help and could communicate in English, were without comorbidities that would prevent participation in cognitive assessments and had mental capacity to give informed consent. A family member, friend or informal carer was recruited, where available and willing to act as an informant, to establish the impact of the PrAISED intervention on them. Follow-up was 12 months following randomisation. The primary outcome was disability in ADL [Disability Assessment for Dementia (DAD)], supported by a range of secondary, intermediate and explanatory outcomes (*Table 2*).

Baseline and 12-month follow-up data were collected through interviews with participants and carers in their own home. Participants were asked to complete monthly exercise calendars and return them by post. Regular reminders were sent. All data were stored in a MACRO Electronic Data Capture (InferMed, London, UK) database managed by the CTU.

TABLE 2 Feasibility study outcome measures

Outcome	Measure	Completed by	Reference
Disability	DAD	Carer	[106,107]
	Nottingham Extended Activities of Daily Living (NEADL) scale	Participant	
Cognition	• Cambridge Neuropsychological Test Automated Battery (CANTAB): Paired Associates Learning (PAL), attention switching task, Spatial Working Memory • Verbal fluency test (from MoCA)	Participant	[108,109]
Dementia severity	Clinical dementia rating	Researcher	[110]
Sitting and standing blood pressure	Automated sphygmomanometer	Researcher	Omron, Milton Keynes, UK
Strength and balance	• The Berg Balance Scale • Leg and hand strength (Lafayette dynamometer, Loughborough, UK), • TUG test and dual-task TUG (while counting backwards in 3s)	Participant	[111,112]
Frailty	The Study of Health, Ageing and Retirement in Europe (SHARE) frailty instrument	Carer	[113]
Physical activity	International Physical Activity Questionnaire Misfit Shine accelerometer	Carer	[114,115]
QoL	• EuroQol-5 Dimensions, three-level version (EQ-5D-3L) • Dementia quality of life (DemQoL) scale; DemQoL-Proxy	Participant Participant and carer	[16,116,117]
Mood	Hospital Anxiety and Depression Scale (HADS)	Participant	[118]
Fear of falling	Falls Efficacy Scale – International (FES-I)	Carer	[119,120]
Carer strain	Carer Strain Index (CSI)	Carer	[121]
Behaviour change	• Basic Psychological Need Satisfaction and Frustration Scale • Behavioural Regulation in Exercise Questionnaire-2 • Healthcare Climate Questionnaire • Clinician's work motivation (Work Extrinsic and Intrinsic Motivation Scale) • Habit questionnaire	Participant	[102–104,122,123]

Between September 2016 and March 2017, 60 participants and 54 family carers were recruited. The study demonstrated that participants could be recruited, retained (49/60, 82% of participants completed follow-up visits) and that acceptably complete data could be collected (46/49, 94% of participants completed DAD outcome questionnaire). The intervention was safely delivered in participants' homes with no serious adverse events (SAEs) related to the intervention. Mean activity per week was 72 minutes, which was considerably short of the required 'dose' of 180 minutes. Progression rules were exceeded: recruitment rate of > 2.5 participants a week; retention of 77% of participants in the study and missing primary outcome data of < 20%.

It was not possible to collect primary outcome data for those participants who did not have an informant; therefore, the availability of an informant was made an inclusion criterion for the definitive RCT.

Collecting blinded outcome data proved impossible in practice. In 86% of cases, researchers ascertained whether the participant had been in an active or control arm of the trial, for example, by seeing equipment in participants' homes, the participants mentioning the therapists visiting or by disclosing which intervention arm they had been in.

Of the two active intervention groups, generally larger effect sizes were seen with high-intensity supervision. The Berg Balance Scale and Timed Up and Go (TUG) tests improved, with large and statistically significant effect sizes, and the DAD improved with a small to moderate non-statistically significant effect size, suggesting that the intervention was not futile. Longer-term follow-up of participants (at 24 months) revealed that participants in the moderate-intensity group did not sustain exercise when supervision discontinued.

The feasibility study was limited by small numbers, with 20 participants in each arm.

Changes following the feasibility study

The intervention for the multicentre trial was based on high-intensity supervision, although it was recognised that for multiple reasons, participants would not always complete the full 50 sessions (e.g. ill health, holidays and other activities). A protocol was developed to identify participants who might not need as much ongoing supervision in order to minimise the expense of the intervention. Calendars were revised to improve the quality of data collected.

We changed the International Physical Activity Questionnaire to the Longitudinal Study of Ageing Amsterdam Physical Activity Questionnaire (LAPAQ).[124,125] We added the Apathy Evaluation Scale (AES) (for Clare Burgon's PhD).[126] We changed the baseline standardised Mini-Mental State Examination[127] to the MoCA,[109] which was measured at baseline and outcome. The scales investigating domains of SDT were dropped. We abandoned efforts to blind researchers collecting outcome data to participant allocation.

Work package 4: process evaluation

Process evaluation protocol: https://doi.org/10.1016/j.maturitas.2019.01.001

Pandemic extension: https://doi.org/10.1136/bmjopen-2020-039305

Process evaluation results: https://doi.org/10.1136/bmj-2023-074787; https://doi.org/10.1093/ageing/afad166

Pandemic impact: https://doi.org/10.1186/s12877-021-02451-z; https://doi.org/10.1186/s12877-022-03239-5; https://doi.org/10.3233/jad-220424

Telehealth remote delivery: https://doi.org/10.3390/ijerph18041717; https://doi.org/10.1002/gps.5730

Realist evaluation: https://doi.org/10.1186/s12877-024-05086-y

The process evaluation aimed to:[128,129]

1. Investigate if the intervention operated as planned, including training and support.
2. Identify facilitators and barriers for intervention delivery and longer-term adherence.
3. Assess intervention acceptability to participants and carers.
4. Examine the delivery of the intervention.
5. Enhance interpretation of results from the RCT.
6. Support dissemination and implementation of PrAISED.

The process evaluation followed guidance from the MRC[130] and used the PHYT-in-dementia theoretical framework (see *Figure 2*) and PrAISED logic model (*Figure 3*) to identify areas of investigation. The study adopted a mixed-methods approach with substudies on implementation, mechanisms of impact and contextual factors. These included quantitative analyses, interviews and thematic analyses.

Implementation

The implementation substudy investigated four areas:

1. Fidelity (consistency of training/intervention delivery).
2. Adaptation (alterations made to the intervention to achieve better fit).
3. Dose (how much training/intervention was delivered).
4. Reach (how many people received the training/intervention).

Data for the implementation substudy were collected during the RCT, recorded on spreadsheets and analysed descriptively. A sample of therapists ($n = 15$) was video-recorded delivering one therapy session each and were assessed against the 14 core PrAISED principles (WP1; *Report Supplementary Material 2*).

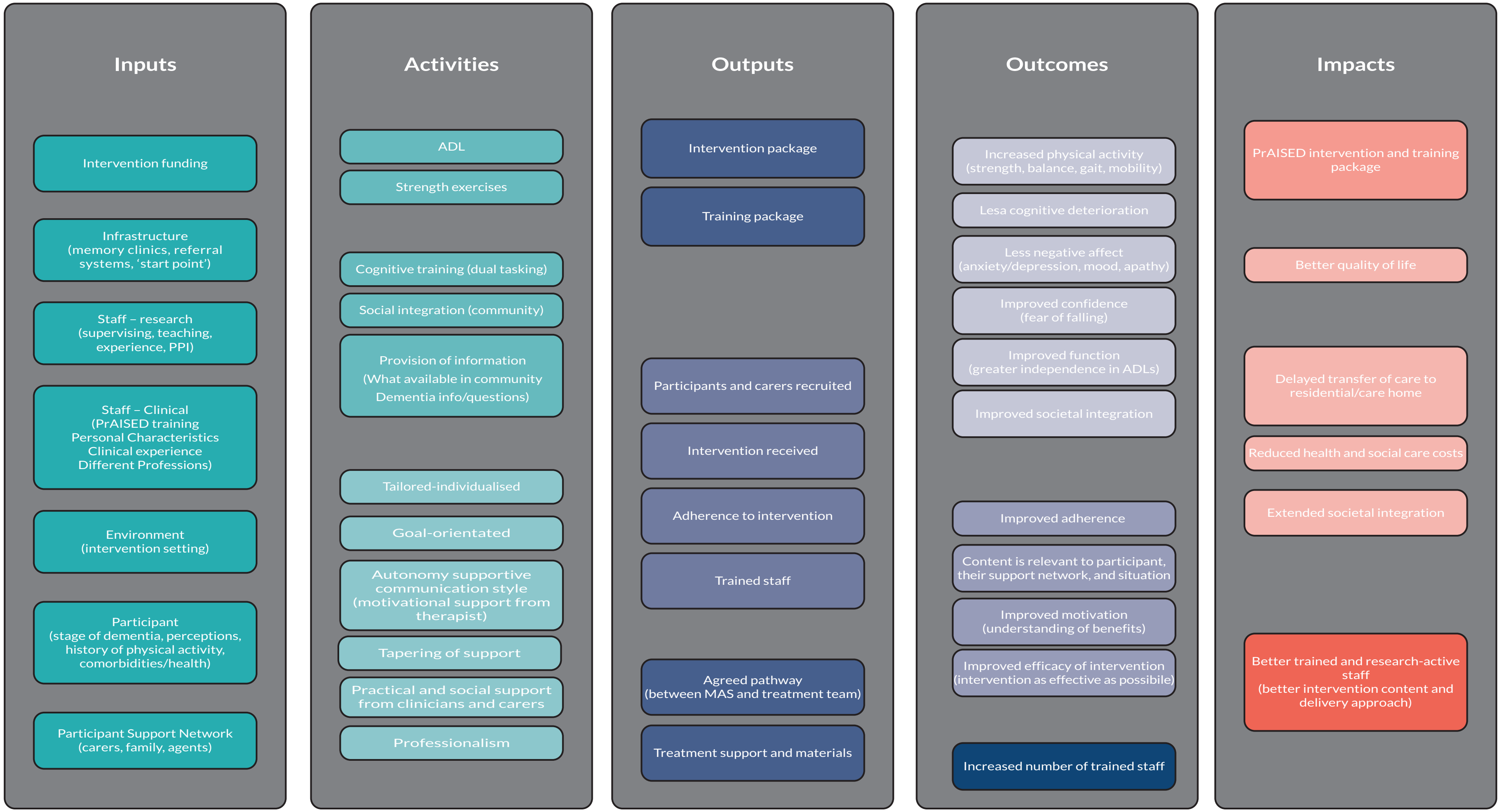

FIGURE 3 The PrAISED logic model. PPI, patient and public involvement.

The intervention was delivered largely as intended and participants engaged well, despite the COVID-19 pandemic. Participants in the intervention group undertook a median of 31 therapy sessions [interquartile range (IQR) = 22–40]. Participants in the control group took part in a median of one session (IQR = 1–1, maximum 3). Mean length of sessions was 71 minutes [standard deviation (SD) = 30; range: 5–220]. Two-thirds were delivered face-to-face (*n* = 1357; 68%). Fidelity of therapy delivery was assessed at 70% against PrAISED core principles. 4040/4863 (83%) expected calendars were returned from intervention participants, and intervention group participants recorded a mean of 482 minutes of PrAISED exercise per month (SD = 705; range: 0–5310; 121 minutes/week).

Mechanisms and context

Data for the mechanisms of impact and context substudy consisted of semistructured interviews with all therapists delivering PrAISED (*n* = 69 interviews with 26 therapists), and a purposive sample of participants living with dementia and carers to reflect diversity (*n* = 88 interviews with 44 participant–carer dyads). Data were collected until conceptual density was reached.

Topic guides were codeveloped by the research team and two PPIE contributors, informed by the PHYT-in-dementia model, which identified variables mediating intervention outcomes. Interview prompts were developed, but a flexible approach was adopted allowing emerging topics to be explored.

Two sets of interviews took place in participants' homes and in therapists' offices at months 4 and 12 of being involved in the PrAISED RCT. Eight interviews with participants and carers were coheld by an academic researcher and a PPIE contributor, the rest by the academic researcher alone. The second set of interviews took place after COVID-19 restrictions were imposed and aimed to ascertain their impact.[129] The original process evaluation topic guides were adapted for the COVID-19 context. A purposive sample of participants and all therapists delivering PrAISED during the lockdown were interviewed. Interviews were undertaken remotely, 2 months into the first national lockdown – May 2020 – and at the end of the lockdown – July 2020. Verbal consent was audio-recorded prior to the interview. Interviews were audio- or video-recorded, transcribed, anonymised and thematically analysed.

Mechanisms of impact and contextual factors affecting participant's experience of PrAISED were determined:

- PrAISED therapy was well received by participants and carers; 80% of intervention group participant interviewees reported a positive experience.
- Participants valued the intervention proactively addressing health issues of concern to them, and as sources 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 carer support.
- Barriers included cognitive impairment, which prevented independent engagement and carryover between sessions; chronic physical health problems, intercurrent acute illnesses and injuries; 'tapering' of supervision; and the COVID-19 pandemic.

Expectations could be unrealistic in terms of hoping for reversal of dementia. Involvement in decision-making was important. Perceiving progress was a strong motivator. The social opportunity of therapists' visits and accessing their expertise on a wide range of health-related topics was valued. 'Social desirability' (working to please the therapist) motivated some. Personal characteristics of participants were important, such as interests and previous exercise engagement, which could act both to motivate and demotivate when performance was diminished from previously. Apathy, forgetfulness, inability to progress therapy over sessions, pain and poor physical health were barriers. Carer and social network support was helpful if available and willing. Attitudes to taking risks varied but could be negative. Stigma and lack of access to community facilities were problems for some.

The COVID-19 pandemic disrupted delivery of the intervention. Remote supervision was mostly conducted by telephone, although at one site, a video-call platform was used successfully.[131] Participants were dependent on access to digital infrastructure and hardware (internet access and devices), and human help in establishing connections to be able to use video call. Therapists reported a changed relationship with family carers, being more dependent on them, and a concern not to overburden them. They responded to an increased demand for social and emotional support, which could distract from exercise performance. Therapists were reluctant or unwilling to progress exercises or activities, that is, make them more difficult, as this often required physical demonstrations and close supervision to ensure that accidents and falls did not occur.[132] We collected evidence that deconditioning was a problem for our participants during COVID-19 lockdowns.[133] However, our intervention group increased physical activity over this period, albeit this could not be directly attributable to therapy support.[134]

Realist evaluation

The process evaluation identified social inclusion as a core outcome of the intervention for participants with dementia. The realist evaluation aimed to determine what 'contexts' and 'mechanisms' generated 'social inclusion' in PrAISED participants. The realist evaluation adopted a mixed-methods design, based on secondary analysis of data from the RCT and process evaluation interviews. The study consisted of three stages: (1) development of context–mechanism–outcome configurations (CMOcs) through analysis of 10% of transcripts and video-recordings of therapy sessions; (2) testing CMOcs, through analysis of 22 dyadic interviews with participants and carers, and 39 interviews with therapists; (3) refinement of CMOcs through triangulation of videos and researcher notes from the process evaluation with RCT data.

Two CMOcs-identified contexts and mechanisms required to generate social inclusion:

- CMOc1: when the therapist tailored therapy sessions to participants' preferences and passions, they were engaged (C). The participants experienced sessions as 'pleasant and fun' (M). This led to high levels of social interactions with the therapist (O).
- CMOc2: some participants perceived achievement of benefits through PrAISED, such as improved balance (C). This boosted their confidence and reduced caregiver risk-aversion/gatekeeping attitude (M). This resulted in participant's increased participation in social activities (O).

We concluded that participants in PrAISED had improved social participation when therapy activities were tailored to their preferences, when therapy support was maintained and when participants perceived improvements as a result of the intervention. Findings suggest the importance of providing therapists with time and skills to boost rapport and connectedness with patients. This is a pre-requisite to enable patients with high support needs, such as people living with dementia, to reduce their risk of social isolation and gain added social benefits associated with human interactions within the context of any social and healthcare intervention.[135]

Limitations

The process evaluation team was not fully independent of the trial team, creating a risk of bias. When the topic guides were developed, the logic model was in an early stage of development with several relevant variables not yet identified. Therefore, areas of investigations in the process evaluation may have been omitted. COVID-19 restrictions and the ensuing remote data collection thwarted collection of more enriched data. Samples, although purposive, were relatively small and may not have reflected the experience of all participants. The video-recording of therapy sessions might have been affected by social desirability of participants and therapists. Similarly, in the qualitative interviews, participants and therapists might have over-reported compliance and benefits of PrAISED. Finally, in the dyadic interviews, some caregivers were reserved in discussing sensitive subjects in the presence of the person they cared for.

Work package 5: multicentre randomised controlled trial

Trial protocol: https://doi.org/10.1186/s13063-019-3871-9

Statistical Analysis Plan: www.nottingham.ac.uk/praised/documents/discussion-paper-series-6-november-2022.pdf, Appendix 4.

RCT results: https://doi.org/10.1136/bmj-2023-074787; Statistical report (*Report Supplementary Material 4*).

Aims

The aim of the RCT was to establish the effectiveness of the PrAISED intervention to improve ADL among older adults with early dementia or MCI at 12-month follow-up. Secondary outcomes included QoL, physical activity, falls and multiple other variables.[136]

Methods

A five-site, multicentre, individually randomised, pragmatic, parallel RCT was conducted. Participants were eligible if they were aged 65 years or over, had a diagnosis of MCI or dementia, a MoCA score of 13–25 (out of 30), a family member, informal carer or friend who knew the participant and had a minimum of 1-hour weekly contact either in person or by telephone/internet, and was willing to act as an informant and participate in the research. Exclusion criteria included a diagnosis of Dementia with Lewy Bodies, a comorbidity preventing participation, anticipated lack of availability over the next year, or life expectancy < 1 year and those who did not have mental capacity to give consent.

Participants were recruited from secondary care memory assessment clinics, GP registers, dementia support groups local to each site, and the NIHR JDR register. Consenting participants were randomised to one of two arms: the intervention arm comprising supervised therapy, or the control arm, comprising falls risk assessment and advice. Randomisation was through a secure internet-based system using a dynamic, adaptive allocation algorithm.[137] A secure web portal held at the NWORTH Trials Unit was used to randomise individuals, 1 : 1, stratified by site, presence of a co-resident and history of previous falls.

Baseline data comprised demographics, medications, medical and falls history and the outcome measures, as in the feasibility study. All baseline data collection was face to face. Participants were asked to complete a daily exercise and falls calendar and return it monthly for months 1–15. Researchers were independent of intervention delivery.

Six months after randomisation, QoL [EuroQol-5 Dimensions, three-level version (EQ-5D-3L), Dementia Quality of life (DemQoL)][137] and service use [short Client Service Receipt Inventory (CSRI)][138] were collected from carers via postal questionnaire, with telephone support if needed.

The main follow-up was after 12 months (± 4 weeks). The primary outcome was carer-informant-rated disability in ADL, measured by the DAD. Secondary outcomes at 12 months were the self-reported Nottingham Extended Activities of Daily Living (NEADL); falls, rate of falling and injurious falls; cognition [MoCA, verbal fluency, apathy evaluation scale and Cambridge Neuropsychological Test Automated Battery (CANTAB)]; QoL (DemQoL, EQ-5D-3L, self- and proxy-assessed); activity (LAPAQ, accelerometers); frailty [Study of Health, Ageing and Retirement in Europe (SHARE) index]; Berg Balance Scale, functional mobility (single- and dual-task TUG test), hand grip strength; fear of falling [Falls Efficacy Scale – International (FES-I)]; mood [Hospital Anxiety and Depression Scale (HADS)]; carer strain (CSI) and carer QoL [EuroQol-5 Dimensions, five-level version (EQ-5D-5L)]. Service use was ascertained via a CSRI (*Table 3*).[138] Researchers collecting follow-up data could not be blinded to allocation.

Intervention

The PrAISED intervention for the RCT was based on the high-intensity supervision pattern detailed in WP3. Feasibility work identified that not all participants needed or wanted 50 sessions over the year, so a decision tree was developed to aid clinician's decisions on the intensity of the intervention delivered (see *Report Supplementary Material 2*). Tapered delivery was continued, and protocols introduced for pauses in case of ill health or periods away from home. An active control comprised one to three visits from a therapist for falls risk assessment and advice.

Outcome evaluation

Follow-up was undertaken by face-to-face interviews with two researchers, who interviewed the participant and carer separately. Follow-up was undertaken remotely via telephone or video calls during the COVID-19 lockdown. Falls, PrAISED activities done independently, service use and hospitalisations were ascertained using monthly self-completed calendars between months 1 and 15 with telephone prompts and support by researchers not involved in delivery of the intervention, where necessary. Injurious falls were adjudicated by two clinicians based on details provided on calendars.

Adverse events

Adverse events (AEs) were collected from the monthly calendars or were reported by participants or therapists.

TABLE 3 Multicentre RCT data collection time points

Scale or measure	Baseline	6 months	12 months	Discontinued from March 2020	Not collected remotely	Completed by
DAD[106]	X		X			Carer participant
NEADL scale[107]	X		X			Patient participant
Demographics	X					Carer participant
Past medical history	X					Carer participant
Medications	X					Carer participant
MoCA[109]	X		X		X	Patient participant
Verbal fluency	X		X		X	Patient participant
CANTAB[108]	X		X	X	X	Patient participant
AES[126]	X		X			Carer participant
Berg Balance Scale[111]	X		X		X	Patient participant
Hand grip strength	X		X		X	Patient participant
TUG test and dual-task TUG[112]	X		X		X	Patient participant
SHARE frailty instrument[113]	X		X		X	Patient participant
LAPAQ[124,125]	X		X			Carer participant
Step count over 7 days (accelerometer)	X		X	X	X	Patient participant
EQ-5D-3L self-completed QoL[116]	X		X			Patient participant
EQ-5D-5L proxy-completed QoL	X	X	X			Carer participant
DemQoL scale[16]	X		X			Patient participant
Dementia utility-weighted items (DemQoL-U)[138]	X	X				Carer participant
DemQoL-Proxy[16]	X		X			Carer participant
HADS[118]	X		X			Patient participant
FES-I[120]	X		X			Patient participant
CSI[121]	X		X			Carer participant
Carer QoL EQ-5D-5L	X		X			Carer participant
CSRI[139]	X	X	X			Carer participant

Note
Calendars were collected monthly from randomisation to 15 months.

Sample size estimate

An initial calculation based on parameters from published literature suggested a sample size of 368 participants (184 per group), with a 23% attrition rate, had 80% statistical power to detect changes in disability outcome (DAD), with an effect size of 0.5 (11 points on a baseline of 70, SD 22).[48,63] A minimum clinically important difference has not been defined for the DAD, but a natural history study in Alzheimer's disease suggested the loss of about one point per month over 12 months.[140]

Statistical methods[141]

For the primary outcome of difference in DAD score between groups, an analysis of covariance (ANCOVA) was conducted using stratification variables (site, co-resident carer and history of falls) and baseline DAD score as covariates. For secondary outcome measures, ANCOVAs were conducted, using the stratification and respective baseline measures as covariates. All analyses were conducted on an intention-to-treat basis. Multiple imputation using chained equations (MICE) was used in the main analysis when appropriate. Effect sizes were standardised as *Cohen's d*.[142] Adjusted mean differences, effect size estimates, 95% confidence intervals (CI) and *p*-values were reported for all analyses. A range of sensitivity analyses were performed, including a complete-case analysis. Falls were analysed as the proportions of participants falling, the incidence rate ratio using a negative binomial regression, and time to first fall using a Cox proportional hazards regression. It was anticipated that any impact of the PrAISED intervention on falls would not be immediate, so the pre-defined efficacy outcome was rate of falling between months 4 and 15.

Ethics and study monitoring

The study was approved by the Yorkshire and the Humber Bradford-Leeds Research Ethics Committee (REC number 18/YH/0059, 18 March 2018). The programme was monitored by an independent steering committee and a Data Monitoring Committee.[143]

Results

Recruitment and follow-up

Between October 2018 and June 2021, we recruited 365 participants with early dementia or MCI and 365 family carers. Eighty-four (23%) were from Bath, 79 (22%) from Derby, 60 (16%) from Lincoln, 23 (6%) from Oxford, and 119 (33%) from Nottingham. Participants were recruited from memory clinics (288, 79%), GP registers (40, 11%), post-diagnostic support services (15, 4%) and the JDR register (22, 6%). Seventy-five participants (21%) did not complete 12-month follow-up. The Consolidated Standards of Reporting Trials (CONSORT) diagram is in *Figure 4*.

Participant and family carer characteristics

Baseline characteristics were similar between groups (*Tables 4* and *5*). Patient participants had median age of 80 years (range 65–95), 58% male, 98% White ethnicity, 68% married and 76% co-resident with their carer. A third (31%) completed a college or university degree. Nineteen per cent had MCI, 39% Alzheimer's dementia, 19% vascular dementia, 16% mixed dementia, 7% other or unknown. Carer participants' median age was 70 years (range 20–94), 73% were female and 65% were spouses. A third (34%) of carers had a limiting long-term health condition.

Assessment of outcome measures

There was no difference between intervention and control on the primary ADL outcome, 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 most secondary outcome measurements, including balance, functional mobility, physical activity or QoL (*Tables 3–6*). Upper 95% CIs excluded small to moderate beneficial treatment effects. There were statistically significant small differences, in favour of the control group, on the dual-task TUG test (*Cohen's d* = 0.48, 95% CI 0.12 to 0.83; $p = 0.01$) and (self-reported) DemQoL (*Cohen's d* = −0.26, 95% CI −0.47 to −0.06; $p = 0.01$), but not DemQoL-Proxy or EQ-5D-3L QoL measures.

Multiple sensitivity analyses showed no differences in results, including (1) complete cases, (2) those completing the intervention before the COVID-19 pandemic, (3) using the interim data collected in the early weeks of the pandemic, (4) correcting for survivor bias, by assigning a DAD score of zero to participants who died, (5) excluding those who terminated the intervention early due to the pandemic, (6) excluding three participants who had MoCA scores at baseline above the upper limit.

About 4.4% of participants reported a confirmed COVID-19 infection. About 82% engaged in social distancing for a median of 116 days (IQR = 37–210) and 47% COVID-19 self-isolated for a median of 71 (IQR = 22–139) days. Results were no different for those reporting, or not reporting, a COVID-19 infection.

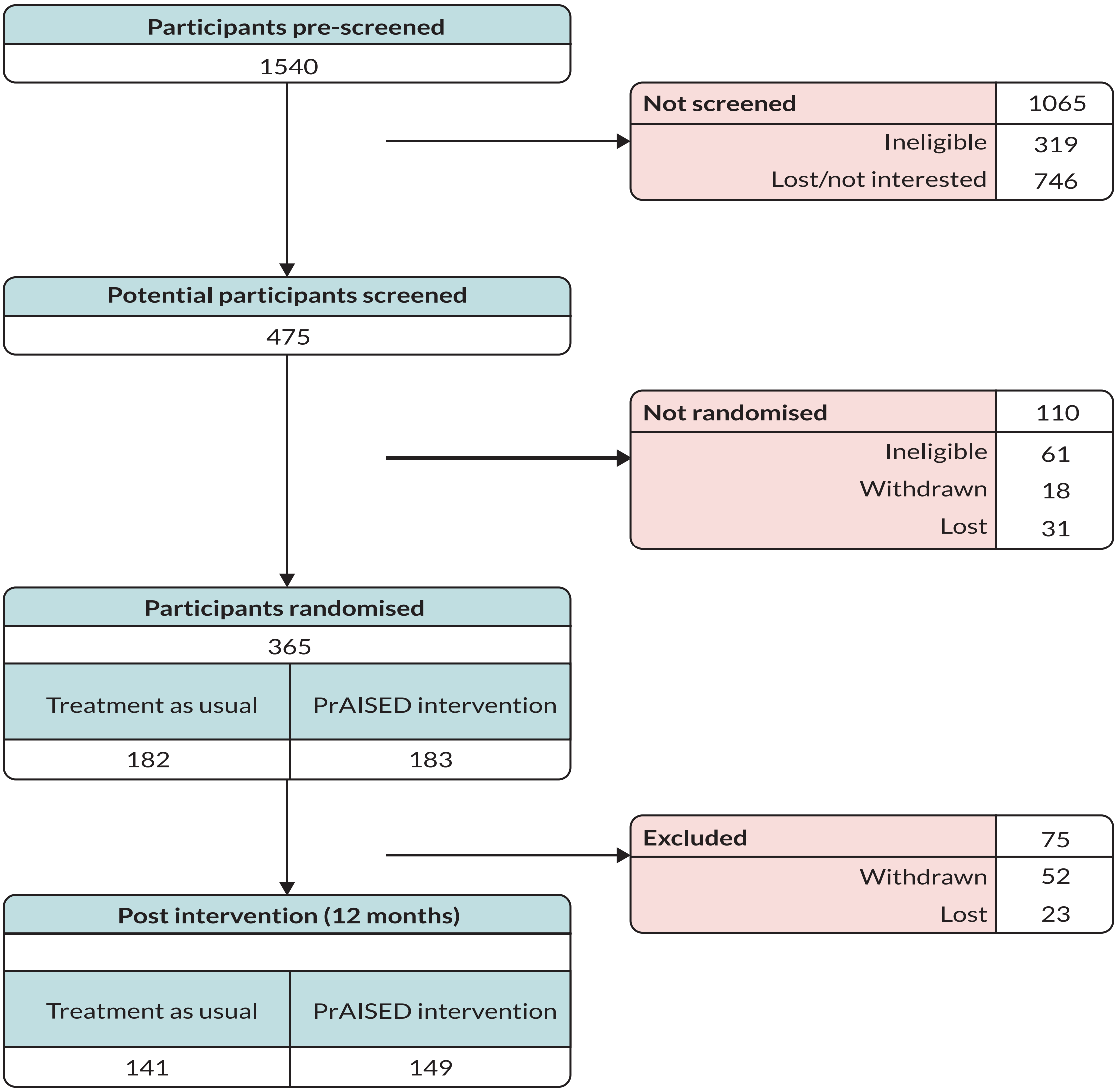

FIGURE 4 Randomised controlled trial CONSORT participant flow diagram.

TABLE 4 Randomised controlled trial baseline variables split by allocation group[1]

	Control *n* = 182	Intervention *n* = 183	Withdrew *n* = 52
Patient participants			
Age median (IQR)/years	81 (75–84)	80 (75–85)	80 (77–85)
Gender female, *n* (%)	73 (40%)	82 (45%)	23 (44%)
Ethnic group White, *n* (%)	179 (98%)	179 (98%)	52 (100%)
Married, *n* (%)	123 (68%)	124 (68%)	34 (66%)
Living alone, *n* (%)	46 (25%)	43 (24%)	17 (33%)
MoCA mean/30 (SD)	19.8 (3.1)	20.0 (3.2)	19.9 (3.2)
Higher education	54 (30%)	59 (32%)	12 (23%)
Diagnosed dementia	142 (78%)	151 (83%)	44 (85%)
Comorbidity count/23 mean (SD)	4.0 (2.0)	3.9 (1.8)	3.9 (1.9)
Number of drugs mean (SD)	6.1 (3.5)	6.1 (3.2)	6.1 (3.4)
Previous fall	95 (52%)	93 (53%)	26 (50%)

TABLE 4 Randomised controlled trial baseline variables split by allocation group (*continued*)

	Control *n* = 182	Intervention *n* = 183	Withdrew *n* = 52
Carer participants			
Husband/wife/partner	119 (65%)	117 (64%)	32 (62%)
Son/daughter	50 (28%)	55 (30%)	16 (31%)
Other	13 (7%)	11 (6%)	4 (8%)
Carer gender female	134 (74%)	131 (72%)	38 (73%)
Carer coresident	136 (75%)	140 (76%)	38 (73%)
Carer long-term medical condition	63 (35%)	61 (33%)	20 (39%)
Carer age (median, IQR)/years	70 (58–77)	70 (58–78)	69 (58–78)

Falls

There were 375 falls in the intervention group and 421 in the control group. 60% of participants in the intervention group had at least one fall compared with 57% in control, OR = 1.1 (95% CI 0.71 to 1.8), $p = 0.6$. There were 73 injurious falls, 38 in the intervention group, 35 in control. At least one injurious fall was reported by 15% of participants in the intervention and 16% in the control groups, OR = 0.91 (95% CI 0.51 to 1.6), $p = 0.8$.

The falls efficacy outcome was falls in months 4–15. There were 79 falls in the intervention group, 200 in control. Falls incidence rate in the intervention group was 1.49 per person-year compared with 2.47 per person-year in control, adjusted incidence rate ratio = 0.78 (95% CI 0.46 to 1.3), $p = 0.3$. Survival analysis showed median time to the first fall was 13 months for the intervention group, 12 months for control, adjusted hazard rate ratio = 0.85 (95% CI 0.50 to 1.4), $p = 0.5$.

Cognition

Tests of gross cognition (MoCA), apathy and verbal fluency showed no difference between intervention and control. Analyses of specific cognitive functions using the CANTAB were underpowered but suggested statistically significant benefits for the PrAISED intervention, with a moderate effect size, on tests of multitasking (an executive function test assessing participants' ability to manage conflicting information) and spatial span (a test of visuospatial working memory capacity; *Tables 7* and *8*).

Harms (adverse events)

There were 167 AEs recorded: 59 in control and 108 in the intervention groups, involving 68 participants: 27 (15%) from control and 61 (33%) from intervention groups. There were 91 SAEs: 29 in control and 62 in intervention, involving 60 participants: 22 (12%) from control and 38 (21%) from intervention groups. None was intervention related. There were 13 deaths: 4 (2.2%) in control and 7 (3.8%) in the intervention groups (OR = 2.3, 95% CI 0.70 to 8.7; $p = 0.3$). There were seven new care home placements: two (1.1%) from control and five (2.7%) from intervention group (OR = 2.4, 95% CI 0.49 to 19; $p = 0.5$). There were 75 hospital admissions: 27 in control and 48 in intervention groups, involving 53 participants: 22 (12%) from control and 31 (17%) from intervention groups (OR = 1.5, 95% CI 0.82 to 2.7; $p = 0.2$).

Limitations

The RCT was severely disrupted by the COVID-19 pandemic. Recruitment was stopped on 17 March 2020, prior to government announcing social distancing restrictions, due to the vulnerability of the patient population. By then, 64 participants had completed the study, 187 were in process and 27 had been recruited but had not commenced therapy. A series of mitigating measures were undertaken, and PrAISED therapists were provided with guidance (see *Report Supplementary Material 3*). A protocol amendment to adapt trial procedures was approved, including delivery of the intervention via telephone or video call.[140] Follow-up assessments were conducted remotely, meaning we could not complete measures requiring physical contact (MoCA, CANTAB assessments, accelerometers, Berg Balance Scale, TUG test). We removed some outcome measures to reduce burden on participants (see *Table 3*). Participants within

TABLE 5 Randomised controlled trial unadjusted scores on outcome measures according to randomisation group[1]

Measure	Group	*n*	Baseline mean (SD)	Follow-up mean (SD)	Difference	Interpretation
ADL DAD/100 Higher is superior	Control	125	77.8 (20.8)	66.4 (24.5)	−11.4	Deterioration
	Intervention	133	77.6 (20.1)	64.2 (25.7)	−13.4	Deterioration
NEADL score/22 Higher is superior	Control	124	16.8 (3.9)	14.1 (4.8)	−2.7	Deterioration
	Intervention	129	16.2 (4.2)	13.9 (4.3)	−2.2	Deterioration
Physical activity (LAPAQ) Higher is superior	Control	118	1483 (1608)	1293 (1430)	−189	Deterioration
	Intervention	130	1395 (1230)	1037 (1224)	−358	Deterioration
Accelerometer – total steps in 7 days Higher is superior	Control	22	21,412 (20,112)	21,694 (17,308)	282	Improvement
	Intervention	21	24,410 (21,081)	20,584 (15,226)	−3826	Deterioration
Berg Balance Scale/56 Higher is superior	Control	58	50.3 (5.5)	46.7 (10.6)	−3.6	Deterioration
	Intervention	66	46.8 (9.6)	46.3 (9.2)	−0.5	Deterioration
TUG/seconds Higher is inferior	Control	69	13.9 (6.7)	14.0 (7.0)	+ 0.1	Deterioration
	Intervention	69	13.7 (4.5)	16.6 (12.6)	+ 3.0	Deterioration
Dual-task TUG/seconds Higher is inferior	Control	62	18.4 (8.3)	20.8 (9.9)	+ 2.3	Deterioration
	Intervention	64	19.7 (11.7)	28.1 (20.0)	+ 8.4	Deterioration
DemQoL/112 Higher is superior; MCID 6	Control	136	90.9 (11.4)	88.9 (14.9)	−2.0	Deterioration
	Intervention	140	89.2 (12.9)	83.7 (15.2)	−5.5	Deterioration
DemQoL-Proxy/124 Higher is superior; MCID 6	Control	135	95.6 (12.9)	90.7 (15.1)	−4.9	Deterioration
	Intervention	145	92.1 (13.3)	90.6 (13.3)	−1.5	Deterioration
DemQoL-U (6 months) Higher is superior	Control	149	0.69 (0.1)	0.72 (0.13)	+ 0.03	Improvement
	Intervention	141	0.72 (0.1)	0.72 (0.13)	0	Deterioration
Self-reported QoL EQ-5D-3L/1.0 Higher is superior	Control	135	0.82 (0.18)	0.75 (0.25)	−0.07	Deterioration
	Intervention	138	0.81 (0.18)	0.75 (0.24)	−0.06	Deterioration
Proxy QoL EQ-5D-5L/1.0 Higher is superior	Control	130	0.80 (0.18)	0.71 (0.23)	−0.09	Deterioration
	Intervention	143	0.79 (0.17)	0.73 (0.19)	−0.07	Deterioration
MoCA/30 Higher is superior	Control	77	20.0 (3.2)	17.5 (4.6)	−2.5	Deterioration
	Intervention	75	20.1 (3.5)	17.3 (5.2)	−2.8	Deterioration
Verbal fluency/words Higher is superior	Control	79	12.3 (4.7)	10.8 (4.8)	−1.5	Deterioration
	Intervention	76	12.0 (4.6)	10.0 (4.4)	−1.9	Deterioration
AES/72 Higher is inferior	Control	121	40.3 (12.0)	44.6 (12.0)	+ 4.3	Deterioration
	Intervention	134	42.4 (12.4)	46.3 (13.0)	+ 3.9	Deterioration
FES-I/28 Higher is inferior	Control	134	10.3 (4.1)	10.9 (4.8)	+ 0.5	Deterioration
	Intervention	138	10.4 (3.9)	11.0 (4.5)	+ 0.6	Deterioration
HADS anxiety/21 Higher is inferior	Control	133	3.7 (2.9)	4.2 (3.6)	+ 0.5	Deterioration
	Intervention	132	4.3 (3.0)	5.0 (3.3)	+ 0.7	Deterioration
HADS depression/21 Higher is inferior	Control	132	3.9 (2.6)	4.8 (3.7)	+ 0.9	Deterioration
	Intervention	132	4.9 (2.7)	5.3 (3.0)	+ 0.4	Deterioration

TABLE 5 Randomised controlled trial unadjusted scores on outcome measures according to randomisation group (*continued*)

Measure	Group	*n*	Baseline mean (SD)	Follow-up mean (SD)	Difference	Interpretation
SHARE frailty index Higher is inferior	Control	71	1.6 (1.6)	1.7 (1.8)	+ 0.1	Deterioration
	Intervention	72	1.7 (1.8)	1.7 (1.8)	0	Deterioration
Hand grip strength right hand/kg Higher is superior	Control	78	24.9 (10.8)	23.6 (9.6)	−1.3	Deterioration
	Intervention	76	22.4 (8.3)	20.9 (7.5)	−1.5	Deterioration
CSI/13 Higher is inferior	Control	125	4.3 (3.3)	4.7 (3.5)	0.4	Deterioration
	Intervention	134	4.7 (3.3)	4.8 (3.5)	0.2	Deterioration
Carer EQ-5D-5L index/1.0 Higher is superior	Control	132	0.88 (0.17)	0.86 (0.17)	−0.02	Deterioration
	Intervention	140	0.85 (0.18)	0.85 (0.16)	−0.01	Deterioration

MCID, minimum clinically important difference.

TABLE 6 Analysis of covariance and standardised effect size estimates for intervention group (with missing data imputed)[1]

Measures	*n*	Adjusted mean difference (95% CI)[a]	*Cohen's d* effect size (95% CI)[a]	*p*
DAD score	365	−1.3 (−5.2 to 2.6)	−0.06 (−0.26 to 0.15)	0.51
NEADL score	256	0.2 (−0.7 to 1.1)	0.05 (−0.20 to 0.29)	0.71
LAPAQ score	365	−167 (−445 to 112)	−0.14 (−0.35 to 0.06)	0.25
Accelerometer – number of steps in 7 days	43	−4030 (−11,028 to 2969)	−0.37 (−0.98 to 0.23)	0.25
Berg Balance Scale	145	1.8 (−0.7 to 4.2)	0.15 (−0.08 to 0.57)	0.15
TUG	138	−2.7 (−5.9 to 0.5)	−0.29 (−0.62 to 0.05)	0.10
Dual-task TUG	126	−7.3 (1.8 to 12.8)	−0.48 (0.12 to 0.83)	0.01
DemQoL	365	−3.8 (−6.8 to −0.8)	−0.26 (−0.47 to −0.06)	0.01
DemQoL-Proxy	365	2.4 (−0.3 to 5.1)	0.18 (−0.03 to 0.38)	0.08
DemQoL-U (6 months)	365	0.01 (−0.01 to 0.04)	+ 0.11 (−0.1 to 0.3)	0.29
EQ-5D-3L index self-reported	365	0.02 (−0.04 to 0.07)	0.08 (−0.12 to 0.29)	0.51
EQ-5D-5L index proxy	365	0.03 (−0.01 to 0.07)	0.15 (−0.05 to 0.36)	0.16
MoCA	155	−0.4 (−1.5 to 0.8)	−0.11 (−0.42 to 0.21)	0.52
Verbal fluency – correct words	155	−0.5 (−1.6 to 0.5)	−0.16 (−0.48 to 0.15)	0.32
AES	365	−0.6 (−2.7 to 1.4)	−0.07 (−0.27 to 0.14)	0.54
FES-I, short	365	0.2 (−0.7 to 1.0)	0.05 (−0.15 to 0.26)	0.64
HADS anxiety	275	0.4 (−0.3 to 1.1)	+ 0.15 (−0.09 to 0.38)	0.23
HADS depression	275	−0.1 (−0.8 to 0.6)	−0.03 (−0.27 to 0.20)	0.78
SHARE frailty index	149	−0.05 (−0.52 to 0.42)	−0.04 (−0.36 to 0.29)	0.56
Hand grip strength/kg	154	−0.9 (−2.9 to 1.1)	−0.15 (−0.47 to 0.16)	0.36
CSI	365	−0.01 (−0.63 to 0.62)	−0.04 (−0.25 to 0.16)	0.69
Carer EQ-5D-5L index	365	0.01 (−0.01 to 0.04)	0.09 (−0.12 to 0.29)	0.37

a Positive values show an effect in favour of intervention group.

Note

Effect size *Cohen's d* interpretation: 0–0.2 = no effect; 0.2–0.5 = small; 0.5–0.8 = moderate; > 0.8 = large.

TABLE 7 The CANTAB cognitive assessment results, unadjusted comparisons[1]

Measure	Group	*n*	Baseline mean (SD)	Follow-up mean (SD)	Difference	Interpretation
MTT RL median congruent/ms Higher is inferior	Control	24	930 (168)	953 (192)	22	Deterioration
	Intervention	26	904 (168)	894 (163)	−9	Improvement
MTT RL median incongruent/ms Higher is inferior	Control	24	1040 (193)	1038 (193)	−1	Improvement
	Intervention	26	1038 (173)	993 (159)	−44	Improvement
MTT RL median switching blocks/ms Higher is inferior	Control	24	1144 (246)	1081 (192)	−63	Improvement
	Intervention	26	1063 (240)	1036 (183)	−27	Improvement
PAL (visual memory) score Higher is superior	Control	27	3.5 (2.1)	2.7 (2.1)	−0.8	Deterioration
	Intervention	29	3.7 (3.4)	3.0 (2.7)	−0.7	Deterioration
PAL number of patterns Higher is superior	Control	27	4.9 (1.3)	4.3 (1.3)	−0.6	Deterioration
	Intervention	29	5.0 (1.5)	4.4 (1.6)	−0.6	Deterioration
PAL total errors Higher is inferior	Control	27	16.1 (7.4)	13.9 (5.8)	−2.2	Improvement
	Intervention	29	17.2 (7.3)	15.5 (8.7)	−1.7	Improvement
SSP lengths forward Higher is superior	Control	28	4.1 (1.2)	3.8 (1.3)	−0.3	Deterioration
	Intervention	30	4.2 (1.2)	4.5 (1.5)	0.3	Improvement

MTT, multitasking test (executive function); PAL, Paired Associates Learning; RL, Rapid Learning; SSP, Spatial Span (visuospatial working memory).

TABLE 8 The CANTAB cognitive assessment results, ANCOVA[1]

Measures	*n*	Adjusted mean difference (95% CI)	Effect size (95% CI)	*p*-value	Interpretation (intervention)
MTT RL median congruent	50	−69 (−146 to 7)	−0.58 (−1.14 to 0.01)	0.07	Better, moderate ES, NS
MTT RL median incongruent	50	−79 (−159 to 1)	−0.62 (−1.19 to −0.05)	0.05	Better, moderate ES
MTT RL median switching blocks	50	−61 (−152 to 30)	−0.43 (−0.99 to 0.14)	0.19	Better, small ES, NS
PAL score	56	0.10 (−1.19 to 1.39)	0.05 (−0.48 to 0.57)	0.87	Same
PAL number of patterns	56	0.09 (−0.67 to 0.84)	0.07 (−0.46 to 0.59)	0.82	Same
PAL total errors	56	1.22 (−3.1 to 5.55)	0.16 (−0.37 to 0.68)	0.57	Same
SSP lengths forward	58	0.81 (0.14 to 1.48)	0.68 (0.15 to 1.2)	0.02	Better, moderate ES

ES, effect size; MTT, multitasking test (executive function); NS, not statistically significant; PAL, Paired Associates Learning; SSP, Spatial Span (visuospatial working memory).

6 weeks of the end of their programme had their final assessment brought forward. An additional interim outcome data collection point was introduced for all other remaining participants, in case no further trial activity became possible. Recruitment and in-person therapy and data collection recommenced after 1 September 2020, if participants were willing, using personal protective equipment, and excluding assessments that required close personal contact or sharing of equipment (including CANTAB cognitive measures and accelerometers). Some remote assessment continued after this time if requested by the participant.

The disruption to intervention delivery, remote data collection and potential changes in participant behaviour due to the risk of COVID-19 could have affected our trial results. However, the impact of COVID-19 also affected participants in the control group.

Work package 6: health economic evaluation

Cost-effectiveness analysis (CEA): https://doi.org/10.1101/2024.12.10.24318781

Social return on investment analysis: https://doi.org/10.1177/23337214221106839; https://doi.org/10.1177/00469580241246468

Economic evaluations were designed as a CEA and SROI which aimed to determine the cost-effectiveness of the PrAISED programme compared to usual care. For CEA, the primary analysis was undertaken from the perspective of the NHS and Personal Social Services following National Institute for Health and Care Excellence (NICE) guidance.[144]

Dementia is a degenerative condition and unlikely to generate quality-adjusted life-year (QALY) gains for comparison with the NICE payer threshold of £20,000–30,000. For dementia, the impact of any innovative service or programme is likely to be as important in relation to the informal carer as it is to the person living with dementia. Carer resilience and well-being of the person experiencing dementia are likely to be some key outcomes of interest, as well as wider health and social care service use. This challenges the traditional health economics toolbox and is the reason why, in the PrAISED study, both a traditional modelling-based CEA with a lifetime horizon and a SROI analysis were undertaken.

Delaying or preventing the onset of dementia by 2 years has been shown to generate economic and societal benefits.[145] However, there is uncertainty about how to design and deliver cost-effective interventions for people with dementia living in the community.[60,146,147] The PrAISED intervention should be considered as a complex, preventative intervention in the sense that the outcomes of the intervention are dependent on exogenous factors.[88] For example, the PrAISED intervention was a tailored programme and required professional skills to deliver the intervention. The outcomes of the intervention depend on patient and carer co-production, that is, adherence and motivation of participants. The MRC recommended using a broad framework for economic evaluation [such as cost–consequence analysis (CCA) and cost–benefit analysis (CBA)] to capture multiple outcomes of complex interventions.[88] SROI is a type of CBA and is becoming commonly performed in areas of complex intervention.[88,148]

The analysis adopted a public-sector multiagency perspective (NHS and social care). The costs of the PrAISED programme consisted of training and delivery costs, health service resource use costs and medication costs. The DAD scale was a primary clinical outcome and was used to generate health status in this analysis. The EQ-5D-3L was used as a health-related quality of life (HRQoL) outcome and generated health utilities and QALYs. All costs and outcomes were collected at baseline and 12-month follow-up period. Within a Markov model using different time horizons, costs and utility values were compared between the PrAISED programme and usual care. Then, the difference in mean total costs divided by the difference in mean total QALYs between the two groups was expressed in terms of the incremental cost-effectiveness ratio (ICER). Deterministic and probabilistic sensitivity analyses were conducted to explore the impact of uncertainty of economic evaluation.

The PrAISED intervention cost was £1236 per participant (£1609 pre pandemic, £1157 pandemic period). For the base-case analysis, a 15-year time horizon was adopted, which exceeded the likely survival in the cohort. Mean costs associated with PrAISED intervention group and usual care per patient were £60,465 and £54,604, respectively. The mean QALYs accumulated were 3.45 and 3.40, respectively. The ICER of the base case was £130,000 per QALY, for the lifetime horizon. The ICER for the pre-pandemic period was £107,374/QALY and £171,637/QALY for the pandemic period. These are higher than the NICE threshold (£20,000–30,000), which means the PrAISED programme was considered not cost-effective.[149] These results reflect those of Khan,[147] who also found that a structured exercise programme was not able to slow cognitive impairment and was not cost-effective.

In probabilistic sensitivity analyses, 40% of the ICER values fell in the north-west quadrant (control dominant). Fewer than 50% of ICER values fell below £30,000/QALY. Cost-effectiveness acceptability curves show that, at a willingness-to-pay threshold of £30,000 per QALY gained, the PrAISED intervention had a 19% probability of being cost-effective. Markov traces for the simulated cohorts showed that after 7 years, 15% of the patients in the standard care arm and 19% of patients in the PrAISED-treatment arm were still alive. At the start of the 15th year, > 99.8% had died.

For complex interventions, SROI identifies and quantifies relevant outcomes and adds financial proxies for these outcomes. This enables SROI ratios to be expressed in monetary units (£). The SROI analysis was undertaken from the societal perspective, which focused on the costs and benefits to those directly affected by the intervention (patient, carer and the NHS). The following steps were undertaken: identifying stakeholders, developing a theory of change, evidencing outcomes, valuing outcomes, calculating costs and estimating the SROI ratio. This SROI analysis was conducted in alignment with the 21-item SROI quality assessment framework tool.[150] The SROI analysis was conducted alongside the PrAISED RCT.[151] Of the 365 patient participants who were recruited with their carers, 64 patient participants completed an in-person programme before March 2020 ('pre pandemic'). Due to COVID-19 restrictions, 301 patient participants completed a 'blended' home exercise programme, as detailed earlier. The SROI analysis compared the pre-pandemic delivery of PrAISED from October 2018 to February 2020, with the pandemic-period delivery from March 2020 to June 2022. Reflecting multiple dimensions of social value, five relevant outcomes experienced by patient participants and carer participants were identified: DAD; FES-I; EQ-5D-5L; CSI and NHS health service resource use (CSRI). All data were collected at baseline and at 12-month follow-up.

In the pre-pandemic period, the PrAISED programme generated a positive SROI ratio of £2.25 for every £1 invested. A higher proportion of PrAISED patient participants reported a 10% or more improvement in DAD, FES-I and EQ-5D-3L scores compared with usual care. A higher proportion of PrAISED carer participants reported less carer strain compared with usual care. PrAISED participants reported less health service resource use than usual care participants.

In the pandemic-period, the PrAISED programme generated a negative SROI ratio. A lower proportion of PrAISED participants reported a 10% or more improvement in DAD and FES-I. PrAISED participants reported more health service resource use.

When the results of the pre-pandemic and pandemic-period programmes were combined, the PrAISED programme generated a positive SROI ratio of £1.27 for every £1 invested. In the PrAISED feasibility study, the SROI ratios of the PrAISED programme were higher than the main study ranging from £3.46 to £5.94 for every £1 invested.[152] A higher proportion of PrAISED practitioners were registered therapists in the feasibility study, which might have resulted in better outcomes for participants. The negative SROI ratio for the pandemic-period programme was likely due to the COVID-19 pandemic and its restrictions, especially lack of access to community facilities after March 2020.

The clinical findings of the PrAISED study showed it not to be effective when compared with usual care, and likewise, a traditional CEA showed PrAISED to have an extremely high cost per QALY ratio, above the NICE threshold. However, when SROI showed that the pre-pandemic PrAISED programme generated a positive SROI ratio, pre-pandemic, PrAISED participants gained social values from increased ADL, improved confidence (less fear of falling), and improved HRQoL, carers acquired social value from less carer strain, and the NHS gained benefits from less healthcare service resource use. These results corroborate the findings from the qualitative PrAISED study that some participants engaged more deeply with PrAISED exercise when therapists were physically present.[101,132] The results of CEA and SROI analysis emphasise the importance of selecting suitable and broad health economics methods that can capture the relevant costs and outcomes of an intervention.

Work package 7: dissemination and preparation for implementation

The aim was to undertake knowledge transfer activities in preparation for implementation of the findings to maximise patient benefit.

The PrAISED programme was designed with subsequent implementation in mind, and underpinned by the use of co-design, including PPIE. Additionally, a variety of knowledge transfer activities were undertaken to disseminate study outputs (*Table 9*):

Implementation study

Implementation study protocol: www.nottingham.ac.uk/praised/documents/discussion-paper-series-7-november-2022.pdf.

In the last year of the programme, a substudy to investigate adaptation and adoption of the PrAISED intervention into clinical practice was conducted. This included four WPs A–D. WPs A and D were informed by the CFIR.[78,79] Approval was received from the Yorkshire and the Humber Bradford-Leeds NHS REC.

TABLE 9 The PrAISED dissemination outputs

PrAISED website and discussion paper series	• The PrAISED Discussion Paper Series, an online journal (ISSN 2399-3502), hosted on the University of Nottingham website (www.nottingham.ac.uk/praised/index.aspx), provided a forum to publish research work not suitable for academic journals • The website provided an openly available repository of all our research outputs to aid dissemination
Social media [Twitter (formerly, Twitter, Inc. – now X Corp. – San Francisco, CA, USA)]	• A Twitter account (https://twitter.com/PrAISEDUoN) was created and, as of 31 March 2023, had 471 followers supporting conversations about ageing, dementia and exercise
Media engagement	• www.nottingham.ac.uk/praised/impact-capture.aspx
Academic publications	• www.nottingham.ac.uk/praised/journal-articles.aspx
Conference presentations	• www.nottingham.ac.uk/praised/impact-capture.aspx • A study conference was held on 10 January 2023 in Nottingham, attracting 68 attendees in person and 44 attendees online www.nottingham.ac.uk/praised/dissemination-event.aspx

- WP A: a pilot service of the PrAISED intervention was delivered in Nottinghamshire Healthcare NHS Foundation Trust from April to November 2022. A mixed-methods study explored implementation of the service and perceptions of future implementation in staff who had delivered the intervention in the pilot and non-pilot sites.
- WP B: a mixed-methods study explored diversity issues in participation in PrAISED and wider research.
- WP C: qualitative interviews investigated how people could remain active after the period of the delivery of the PrAISED programme. Results are presented with WPs A and D.
- WP D: qualitative interviews were conducted with key stakeholders to explore the commissioning and implementation of PrAISED, which informed the production of a guide for developing a business case.

Work package A: pilot service[153]

Preprint https://doi.org/10.1101/2023.05.24.23289730

Pilot service

Seven staff members delivered the pilot service (two physiotherapists, two occupational therapists and three RSWs), three of whom had also participated in the PrAISED RCT. New team members received a shortened version of the PrAISED training. The pilot aimed to recruit 20 participants from a memory assessment service and used an adapted intervention for delivery over 6 months based on the 14 core principles of the PrAISED intervention.

Participant and intervention data were collected. Semistructured interviews were conducted with the seven members of staff.

Eleven patients were recruited (55% male; mean age 78, range 68–85; 91% White British). Staff delivered a total of 230 visits (mean 21 visits per participant, range 5–38) with a mean visit duration of 82 minutes (mean range 68–91 minutes). The number of visits varied depending how early in the pilot they were referred to the service.

Interview findings suggested that establishing operational processes for the pilot service across the trust was more complicated than in the RCT, and future work would need adequate time resource to address this. The pilot service did not achieve target recruitment which was thought to relate to the short-term nature of the pilot, preventing time to embed processes into clinical activities; high turnover in the referral team; and time constraints during appointments with newly diagnosed patients to impart the breadth of information required.

Staff enjoyed delivering the service and being involved early in a patient's dementia journey, and felt they had a valuable role in rehabilitation. Challenges to delivery included the small team and the part-time nature of their roles. They felt the pilot service was more like normal practice with greater flexibility for patients to join the service or to leave if there was poor engagement or motivation.

The shorter duration of the intervention (6 months vs. 12 months in the RCT) meant there was less focus on rehabilitation activities, such as dual-task training, and more focus on risk assessment/management, providing written materials, quick strategies such as physical elements/exercises and signposting to other services to provide long-term support. Goal-setting continued, but due to time constraints, these had to be prioritised to fit with the shorter time frame.

Staff perceived patient benefits from the 3- to 6-month intervention but noted a greater dependency on referral to other services for sustainability. They noted that the service was well received by patient participants, with most providing positive feedback and perceived improvements in confidence, motivation, balance and strength and reductions in loneliness.

Future implementation

Eight interviews (four managers and four delivery staff) were conducted with staff members from the non-pilot sites involved in the RCT and were combined with the interviews from the pilot to explore wider issues relating to the future implementation of PrAISED. Six key themes were identified:

- *Need* – PrAISED was viewed as a holistic and preventative option for patients immediately post diagnosis, the home-based nature improved access to the service and gave a more informed assessment of a participant's home environment.
- *Acceptability* – both staff and patient participants liked the intervention. Early intervention immediately post diagnosis, and the longer duration of the intervention, were thought to be important for supporting participants and preventing deterioration.
- *Referrals* – there were mixed views about which patients should be eligible, the timing and process of referrals to PrAISED. Some thought these were appropriate as they stood, whereas others felt that some patients were 'too well' and did not need support to be active immediately post diagnosis. Some thought the timing of offering the intervention may be overwhelming at the point of the diagnosis and that it might be better offered at a later stage. It was suggested that there could be other pathways by which patients could be referred to the service, for example, via GPs, or other services.
- *Intervention design* – staff liked the 12-month intervention duration but were unsure how it would fit with usual clinical pathways. The flexibility and tailored approach to visits was important.
- *Effective delivery* – management support, co-ordination and supervision along with team working and regular communication were critical in the effective delivery of the intervention. It was thought that staff needed to be skilled with experience of dementia.
- *Signposting/services* – using team knowledge and knowledge from across the therapist networks was important to understand which services were available, and where, to optimise long-term activity beyond the end of the intervention.

It was possible to deliver PrAISED as a service in practice, with real-world adaptations. Operational challenges were identified, and the shorter intervention duration meant that participants required more onwards referrals or signposting to other services for maintenance. Staff and patients enjoyed taking part in the PrAISED service and reported perceived benefits. Future implementation work would require attention to referral processes; maintaining the intervention principles; management support, communication and team working; staff skills; sharing of knowledge to deliver the intervention; and knowledge of other services to facilitate signposting and support patients longer term.

Work package B: diversity[154]

Preprint https://doi.org/10.1101/2023.09.06.23295133

The PrAISED RCT participants lacked ethnic and socioeconomic diversity. An exploratory mixed-methods study was conducted to investigate disparities between the PrAISED RCT population, and the population referred to memory assessment services at the Nottinghamshire study site. Data were collated and summarised on ethnicity and deprivation, and healthcare professionals (HCPs), researchers and members of Black and South Asian communities were interviewed to explore barriers to participating in research.

National Statistics Census 2021 data indicate that 18% of people in England were from a Black, Asian, mixed or other ethnic group. Fewer than 2% of the PrAISED RCT sample were from a non-White ethnic minority background. One-third were graduates, and a third lived in areas of least deprivation. Referrals to memory services in Nottinghamshire included people from diverse socioeconomic backgrounds, with 7.3% being from non-White ethnic minority communities. However, for the Nottingham and Nottinghamshire PrAISED participants, 5% were from an ethnic minority background and 42% were from an area that was within the least deprived 10% in the county (*Figure 5*).

Interviews identified barriers to accessing health care and rehabilitation and to involvement in research. Healthcare barriers included lack of awareness of dementia, mistrust, stigma, fear and lack of culturally appropriate services. For research barriers, common themes were recruitment routes, awareness of research, language and recruiter beliefs. Barriers to rehabilitation research were also explored and identified lack of culturally appropriate language, more cultural-specific barriers, and lack of representation hindered participation.

Work package D: commissioning[155]

https://doi.org/10.1101/2023.03.26.23287750

The barriers and facilitators for commissioning and implementing dementia-friendly exercise and physical activity interventions, such as PrAISED, were explored in 14 semistructured interviews with commissioning managers, partnership managers, charity representatives, commercial research specialists, academics and HCPs.

Participants identified a need for further support for people diagnosed with dementia, and their caregivers, after a dementia diagnosis. The main barriers to commissioning and implementing interventions were the cost and financial implications, and who would be responsible for this; the culture of commissioning, which tends to focus more on the short term and crisis management, rather than on preventative interventions which could be more cost-efficient in the long term; lack of available resources, including workforce, time, capacity, available providers and funding; and engaging people living with dementia in physical activity due to fear and anxiety, perception of it being a risky activity and lack of support or poor awareness of available services.

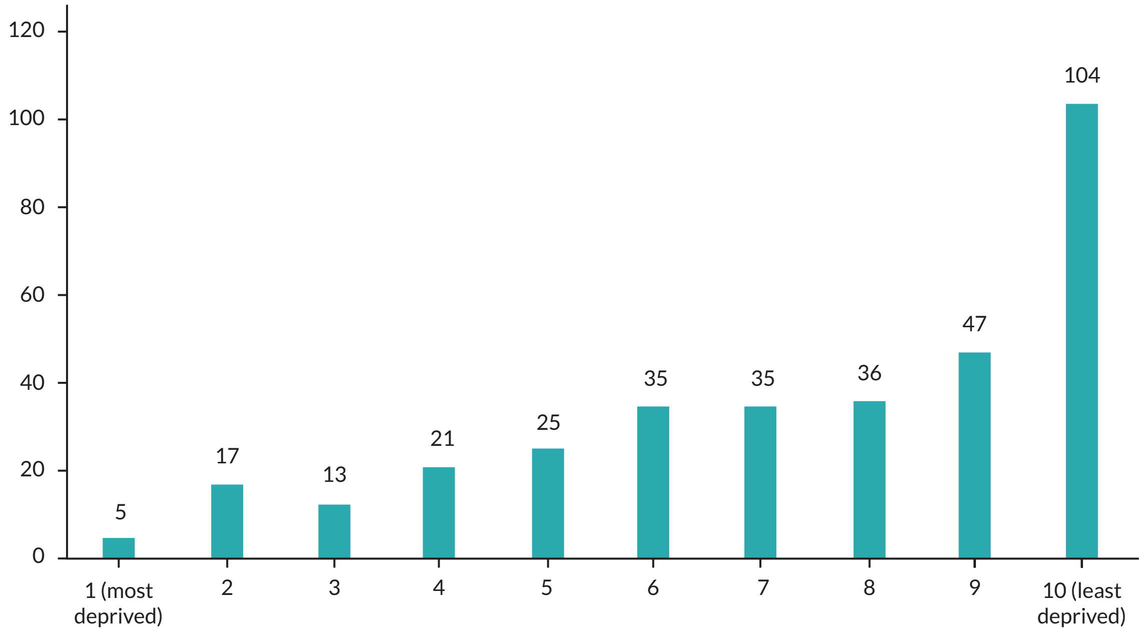

FIGURE 5 Socioeconomic characteristics of participants: distribution by postcode Index of Multiple Deprivation.

The main facilitators were having evidence of effectiveness and cost savings of the intervention; intervention adaptability to local systems and the potential to embed the intervention in existing services; partnerships and connections with other organisations and stakeholders to deliver a collaborative approach; external policy and incentives which support commissioning and implementation of dementia services; and the use of an existing workforce to deliver the intervention, helping to keep costs down and to build capacity by upskilling existing staff, or using other professionals, such as exercise instructors, to deliver the intervention to reduce costs and the demand on the existing workforce.

Inter-relationship of work packages

The inter-relationships between the PrAISED WPs are presented below (*Table 10* and *Figure 6*).

Discussion

Summary of findings

- We developed and refined a tailored, exercise-based, functional activity-orientated therapy intervention, called PrAISED, for people with mild dementia and MCI. It delivered up to 50 therapy sessions over a year, encouraged additional exercise between supervised sessions and tapered supervision to encourage self-directed continuation of exercise. This constituted a moderate to high-intensity, long-duration programme. Tailoring took account of individual history, personality and abilities, problems, interests, family and other resources. Fourteen core principles were defined to guide tailored therapy. A logic model was developed. Exercise was intended to reduce risk of falls, and to provide the necessary strength and balance to undertake ADL and access community facilities. Delivery was by physiotherapists, occupational therapists and unregistered RSWs. Development methods were systematic, and

TABLE 10 Inter-relationship of WPs

WP1 intervention development	• Adherence and motivation work (WP2) informed the intervention • The intervention was tested and refined through the feasibility study (WP3) • The process evaluation (WP4) fed back into intervention development • The intervention and training material were tested in the main RCT (WP5) and disseminated in WP7 • Intervention costs contributed to the economic evaluation (WP6)
WP2 motivation and adherence	• Provided a behaviour change framework for intervention delivery and training (WP1) • Formed the core qualitative work alongside the process evaluation (WP4)
WP3 feasibility study	• Provided evidence to support progression to the definitive RCT (WP5), and changes to the protocol to enhance the trial • Helped refine the intervention development and clinician training (WP1) • Participants were interviewed and observed in the adherence and motivation (WP2) and process evaluation work (WP4) • Informed health economic evaluations (WP6)
WP4 process evaluation	• Intervention development team (WP1) supported the identification of areas of investigation in the process evaluation (e.g. fidelity) • The behaviour change model (WP2) provided theoretical underpinning to process evaluation • Data for the process evaluation implementation substudy were collected through the RCT (WP5) • Identified SROI outcomes for the health economic evaluation (WP6) • Developed the PrAISED logic model • Identified areas to be addressed in clinical practice for dissemination and implementation (WP7)
WP5 multicentre RCT	• Used the intervention developed in WP1 • The RCT protocol was refined following the feasibility study (WP3) • A process evaluation alongside the RCT was undertaken in WP4 • Provided data for the health economic evaluation WP6
WP6 health economics	• Relied on data and models from all WPs • Uncovered quantified evidence of pandemic impact on the RCT results
WP7 implementation and dissemination	• Knowledge transfer for all WPs • Demonstrated how a service might work in practice, and the necessary conditions for it being commissioned

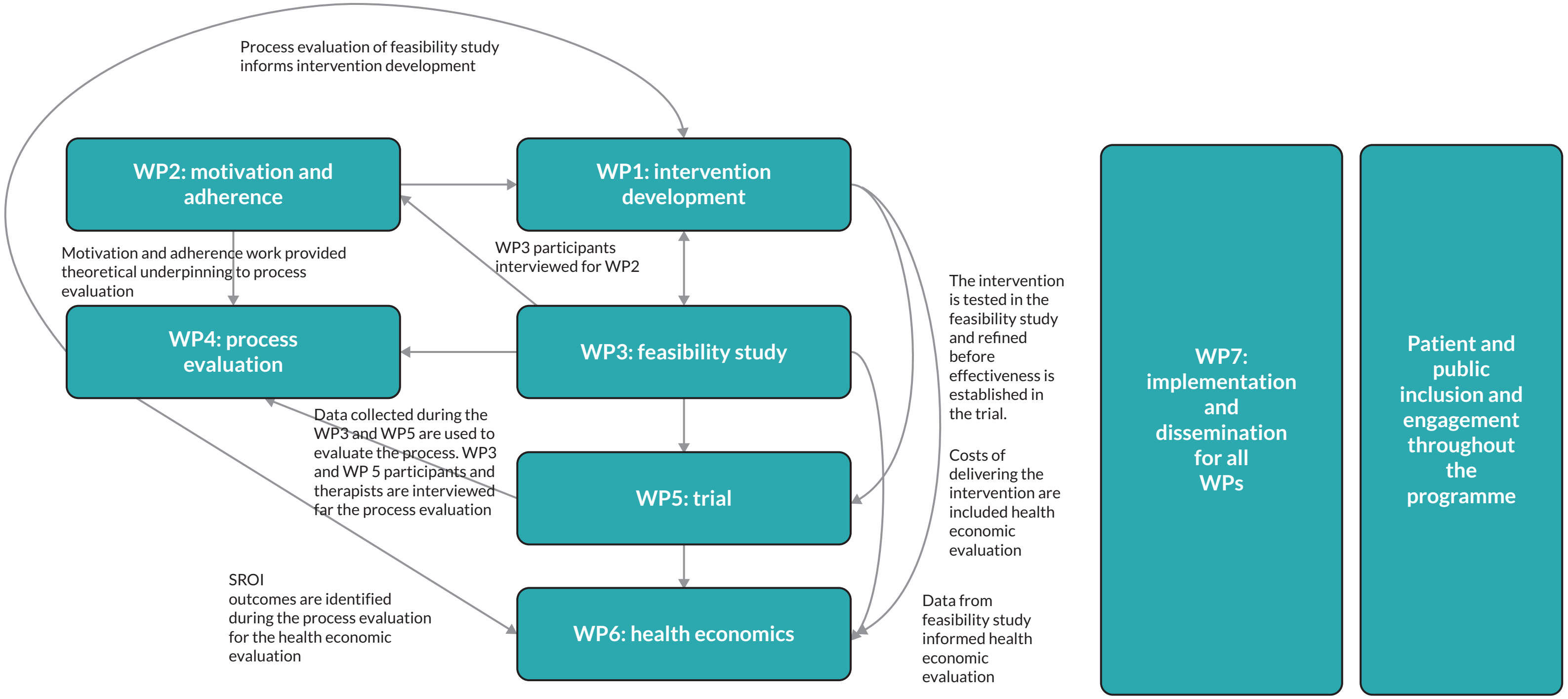

FIGURE 6 The PrAISED research diagram.

refined through experience, especially in the feasibility study. A training programme for therapists was designed and delivered, along with real-time support via regular teleconferences. An intervention manual was published.

- We reviewed behaviour change frameworks for people living with dementia, and adapted SDT to support the intervention. This posits the importance of autonomy, relatedness and competence, leading to 12 practical approaches to support motivation. 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 RCT.
- We undertook a two-site, three-arm feasibility study. We compared the fully supervised PrAISED intervention with a 3-month programme, and a control condition comprising brief falls assessment and advice. A battery of health status measures was administered at baseline and 12-month follow-up, including disability in ADL, habitual physical activity and QoL. We successfully recruited 60 participants, of whom 45 completed the intervention and provided outcome data. There were no serious, related AEs. Missing data rates were satisfactory, apart from some scales that were investigating SDT, which were subsequently dropped. We made some minor adjustments to eligibility criteria and outcome scales. We found that participants were unable to adhere to the programme in the absence of supervision. We implemented higher-intensity supervision in the RCT but developed an algorithm to plan intensity, considering participant's ability to undertake activities independently of professional staff.
- We undertook a five-site, two-arm RCT, powered to detect a moderate effect size on the DAD scale. Both service delivery and research were severely disrupted by the COVID-19 pandemic. Recruitment was delayed, some follow-up was undertaken remotely, some therapy intervention was delivered by telephone or video call. Community facilities and activities became unavailable or unattractive to vulnerable people. We recruited 365 participants. Intervention arm therapy comprised a median of 31 sessions and 68% face to face. Intervention group participants reported undertaking an additional mean 121 minutes of exercise per week. Two hundred and ninety (79%) participants were followed up. There were no significant differences on the primary outcome, DAD score, physical activity, balance, QoL, cognition or a range of other measures. Upper 95% CIs excluded even small benefits. Rate of falling reduced by 22%, but this was not statistically significant. Results did not change in a range of sensitivity analyses.
- A process evaluation evaluated fidelity, reach and mechanisms. Eighty-eight interviews were undertaken with participants, carers and staff. PrAISED was popular among participants and clinicians, and many gave examples of how their lives had been improved. Cognitive and physical impairments, and fear of falls or getting lost, prevented independent engagement. Tapered support was ineffective in promoting self-directed activity and acted as a barrier to continued engagement. Family members played a major role in encouraging participation. A realist evaluation considered mechanisms behind social benefits, confirming the importance of personalisation, therapeutic relationship, ongoing professional support and confidence resulting from perceived improvement.
- An economic evaluation considered a within-trial CEA, a Markov model of potential effects across a 7-year estimated lifespan and a SROI study. The cost-effectiveness study showed a cost/QALY over £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.
- We undertook four small-scale implementation studies. 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 of what was anticipated. We investigated reasons behind poor recruitment of ethnic minority participants, finding that they mistrusted the health service and research, and, in some cases, communities did not acknowledge dementia. We interviewed commissioners and other key stakeholders to develop guidelines on constructing a business case for implementing exercise and post-diagnostic support programmes.

Successes and challenges, strengths and limitations

The programme structure enabled a systematic and thorough approach to intervention development and evaluation, including examining behaviour change frameworks, which have been previously neglected in dementia. The multicentre RCT was supported by a feasibility trial, process and realist evaluations and a health economic study, which used novel methodology to undertake a SROI analysis. We investigated implementation factors. These elements were successfully delivered.

The main weakness was the disruption caused by the COVID-19 pandemic. Pandemic lockdown commenced when 301/368 participants had been recruited; 187 were mid trial, and 64 had completed the trial. We suspended and restarted the trial, using remote methods to sustain support for active intervention participants who were able.

Restrictions continued after we restarted. For many participants, the intervention was not what was designed or intended, infection concerns and social restrictions dominated, and community facilities that were promoted by PrAISED became unavailable or unattractive to participants.

We became aware that our outcome measurement scales may not have been well aligned with the ways in which the intervention provided benefit. We put a lot of effort in intervention design to trying to improve executive function, possibly reflected in the CANTAB results. The DAD includes elements of initiation and maintenance, which seemed well-matched to this. However, DAD prioritises independent performance, over supported or adapted performance. We did not have direct measures of participant satisfaction, dependency or difficult-to-measure psychosocial variables, such as personhood, inclusion, enjoyment, occupation, connectedness or relationships. Despite our large number of outcome measures, there appears to have been a divergence between what participants told us about the programme and what we measured.

The capacity of community health and mental health services to support research was challenged, regardless of the additional impact of the pandemic. Therapists liked being part of the study, finding the intervention different, interesting and more positive than much of their usual work which was focused on resolving crises. However, there was insufficient work for full-time employment of dedicated staff, who were therefore often drawn from established clinical teams, which often carried vacancies, and had competing and sometimes urgent calls on their time. Staff turnover was unexpectedly high, with 63 clinicians (23 occupational therapists, 18 physiotherapists and 22 RSWs) taking part overall, across 5 sites, over 2 years, highlighting the precarity of their services. It is possible that outside of a research study, scheduling or continuity might be better but would still rely on adequate staff availability to deliver. We had no specific evidence that lack of continuity diminished intervention quality, but that might have been the case.

Our participant population lacked ethnic diversity, being overwhelmingly White, and socioeconomic diversity, being predominantly well-educated and economically advantaged. There was also a disproportionate proportion of men recruited (58% compared with about 35% overall among people living with dementia).

Ethical issues

All activities involving patients and family members were approved by a REC and local research governance procedures. We supported the right of people living with dementia to be involved in and to contribute to research. In the trials, we chose to study people who retained mental capacity to consent, despite a dementia diagnosis, in keeping with the mild stage of disease which we were studying. 'Process consent' was used to ensure that the participants were willing to continue participation at each contact. We developed a protocol for managing any cases where mental capacity was lost, based on the assumption that, having agreed to take part, the individual would have wanted to continue, but confirming this with a personal consultee who was identified in advance. The right of withdrawal was emphasised and was used in the trials, usually in the face of deteriorating health. The research was considered to be low risk, given that the exercise recommendations were within World Health Organization (and UK) guidelines for exercise in older people. Ethical issues were mostly generic, including consent, burden, privacy and data security. The pandemic added risks of viral transmission, and rigorous measures were taken to mitigate this.

Interpretation

We are faced with four possible explanations for our results:

- The PrAISED intervention did not work.
- We studied a population who could not benefit.
- The outcomes we measured did not capture the positive effects of the intervention.
- The COVID-19 pandemic disrupted both intervention and research to an extent that the results are invalid or uncertain.

Participants undertook supervised therapy, and reported additional exercise between supervised sessions, but less than might be expected to change balance or executive function. Cognitive impairment and physical comorbidities remained significant barriers to engagement. Motivational strategies were only partially successful.

Our participant population may have been health-aware, following healthy living advice and better able to adapt to problems of dementia than much of the population. Scope for further improvement may have been limited.

Benefits of intervention could be seen in terms of enhancing personhood (identity, comfort, inclusion, attachment, occupation) rather than independence, activity, mood or QoL. Our outcome set was broad but was overwhelmingly biomedical in outlook. This may have caused us to miss real differences between our trial intervention groups.

We continued and completed the trial despite major disruptions caused by the pandemic. Participants told us that they appreciated the ongoing participation and support, and we collected some evidence that PrAISED arm participants were more physically active than control participants.[133,134] Therapists reported that a lot of remote intervention activity was information-giving and emotional support, rather than PrAISED therapy or exercise.[132] On the other hand, the pandemic was difficult for many older people, and even limited remote support afforded might have been beneficial. The only direct comparative evidence we have on pandemic effects comes from the economic SROI analysis, which suggested that the intervention may have been cost-effective prior to the pandemic, but that this was wholly negated by pandemic restrictions, in particular through the loss of access to community activities and facilities.[151]

It may be that it is impossible to slow or reverse the functional decline seen in dementia, in which case we need to adopt a new mind-set in providing support and health care after a dementia diagnosis. There remains a need for postdiagnosis support, which was identified by many stakeholders in our qualitative research.[101,153]

Patient and public involvement and engagement

We embedded PPIE at every stage of the research cycle. We worked in collaboration with the University of Nottingham's Dementia, Frail Older Person and Palliative Care PPIE group. The PPIE group was established in 2012, meets nine times a year, was led by a coinvestigator (Sarah E Goldberg) and chaired by research fellows. The PPIE group currently has 13 members (4 male; 2 from an ethnic minority), who have experience of dementia and an interest in research.

Governance

Patient and public involvement and engagement contributors

- Worked on the PrAISED programme since the first application in 2012. One served as coinvestigator.
- Were members of the Programme Management Group, attending monthly meetings.
- Helped interview research fellows.

The membership of the Programme Steering Committee included an Alzheimer's Society research monitor and the manager of the local Alzheimer's Society branch.

Design

- The PPIE group, representatives from the Alzheimer's Society, Age UK and individuals with personal experience of dementia contributed to the research design, including the non-viability of third-sector service delivery, outcome measures and acceptability of the research to people with dementia and carers.
- PrAISED programme updates were presented annually to the PPIE group to seek their advice and update them on progress.

Intervention development

- The intervention, design and evaluation of the training programme was co-created with PPIE members, clinician and other stakeholders.
- Maureen Godfrey and Marianne Dunlop attended WP1 meetings and provided PrAISED research delivery staff with pragmatic and person-centred approaches to problem-solving during the study. To ensure intervention acceptability,

the PrAISED therapists had a 'dry run' of delivering the intervention to Maureen Godfrey, Marianne Dunlop and a third member of the public.
- Maureen Godfrey and Marianne Dunlop co-produced the PrAISED logic model with members of the PrAISED team.

Qualitative research

- Eight interviews with participants and caregivers were coheld by Claudio Di Lorito and Maureen Godfrey or Marianne Dunlop.[156]
- Maureen Godfrey and Marianne Dunlop were part of the qualitative data analysis team, were trained in qualitative analysis and gave their lived experience to the interpretation of data.

Study processes

- Maureen Godfrey or Marianne Dunlop reviewed patient- and carer-facing documentation to ensure it was appropriate.
- Maureen Godfrey and Marianne Dunlop did a 'dry run' of the patient and carer interview process to ensure it was acceptable and not unduly burdensome.
- Maureen Godfrey and Marianne Dunlop advised on the revised evaluation protocols related to changes following COVID-19 restrictions and provided advice on restarting recruitment following easing of lockdown restrictions.
- Maureen Godfrey and Marianne Dunlop contributed to the development of the service leaflet in the implementation substudy (WP7).

Health economics

- Maureen Godfrey contributed to the SROI health economic analysis.

Dissemination

- Maureen Godfrey and Marianne Dunlop co-authored 11 research papers, 1 discussion series paper and 5 conference abstracts.
- Maureen Godfrey and Marianne Dunlop presented at two PPIE conferences and the Programme Steering Committee on their experience of conducting qualitative process evaluation interviews.
- Maureen Godfrey and her husband were videoed doing the PrAISED exercises [YouTube (YouTube, LLC, San Bruno, CA, USA) www.youtube.com/watch?v=BXNHm9Nj1pk] with over 3075 views to date.
- Maureen Godfrey and another member of the public were professionally photographed doing the PrAISED exercises, which were used for the PrAISED information sheets and other promotional materials.

Maureen Godfrey received two awards for her outstanding PPI work: the University of Nottingham Community Volunteer of the Year award and a publication award for a paper on co-researching.

We recognise that our research would have been strengthened by working with more people from ethnic minorities and socioeconomically disadvantaged backgrounds. While PPIE in the PrAISED programme was extensive, our lack of attention to diversity might have impacted our recruitment of participants from diverse backgrounds.

Equality, diversity and inclusion

People living with dementia and disabilities and older people are, in general, disadvantaged, seldom heard, and their problems are under-researched. This programme helps to address this inequity.

Our study sites were nationally representative in terms of economic and ethnic composition. Within the study, we faced three problems with equality, diversity and inclusion (EDI): (1) one-third of our trial participants came from the top decile (10% least disadvantaged) of the Index of Multiple Deprivation (IMD) postcodes, (2) 98% of our participants were of White ethnicity and (3) our participants were disproportionately male.

We investigated this further as part of our implementation study:

- A researcher of South Asian heritage conducted interviews and groups meetings among Asian community groups, finding that both health and research establishments were not trusted, and diagnoses of dementia were not widely accepted.
- We implemented PrAISED as a pilot service available to Memory Assessment Service users in a deprived locality. Uptake was unfortunately poor, potentially due to the time required for operational process to embed in a hard-pressed service, with rapid staff turnover.

Trial participants are volunteers and are likely to be better educated and motivated than the average, but this means that they are unlikely to be representative of the population as a whole. Our sites were quite diverse: rural, urban and geographically spread. Recruitment to trials is not easy, and we can only work with the willing. We had to adjust our recruitment criteria (we reduced the lower limit of MoCA score from 15 to 13), extended our recruitment routes (initially Memory Assessment Services, later GP dementia registers) to ensure that recruitment rates were adequate, and, within the infrastructure that we had available, could not any further choose or target who participated. Our process evaluation found that identity (as an active person), or a personal history of undertaking sports, were motivators for participation, and this may have explained the male preponderance.

Context

Guidelines based on observational epidemiology have suggested that up to 30% of dementia may be preventable, or that its progression might be slowed, with exercise being a key proposed intervention.[157]

Two trials of moderate-intensity exercise in sarcopenia and frailty have shown small (20% relative risk) reductions in risk of incident mobility disability, among people who are cognitively well.[158,159]

Multiple systematic reviews have reported on the effect of exercise interventions on cognition, and ADL in dementia.[160–162] The evidence base was weak, and findings inconsistent, depending on the studies included. In addition, there are a growing number of well-performed, adequately powered trials (*Table 11*). The FINALEX trial of intensive (1 hour, twice a week, 52 weeks' duration) home-supervised exercise, showed dramatic slowing in loss of ability in ADL, and a halving of the rate of falls, but little impact on cognition.[63] Two subsequent 4-month-duration moderate to high-intensity exercise studies showed no benefit in either cognition or ADL.[163,164] The Community Occupational Therapist in Dementia (CoTID) study showed that community-based occupational therapy over 10 weeks could improve ADL, but this was not replicated in two subsequent trials of the same intervention.[60,165,166] The Goal-oriented cognitive Rehabilitation in Early-stage Alzheimer's and related dementias Trial (GREAT) of cognitive rehabilitation showed that

TABLE 11 High-quality exercise and functional activity trials for people living with dementia

Study	Intervention	Outcome
Graff 2006 (COTiD)[60]	OT, 10 sessions in 5 weeks	ADL better
Voigt-Radlhof 2011[163]	OT, 10 sessions in 5 weeks	No benefit in ADL
Pitkala 2013 (FINALEX)[63]	PT, 1 hour 2 times/week for 52 weeks	Less ADL decline, fewer falls
Hoffman 2016[161]	Exercise 3 times/week for 4 months	No benefit in ADL
Lamb 2018 (DAPA)[162]	Exercise 3 times/week for 4 months	No benefit in ADL
Clare 2019 (GREAT)[165]	Cognitive rehabilitation, 6 months	No benefit in ADL
Mountain 2022 (JtD)[166]	OT, 16 sessions in 12 weeks	No benefit in ADL
Wenborn 2022 (VALID)[164]	OT, 10 sessions in 10 weeks	No benefit in ADL
Harwood 2023 (PrAISED)[1]	31 sessions OT/PT, 52 weeks	No benefit in ADL

JtD, Journey through Dementia; OT, occupational therapy; PT, physiotherapy.

active intervention helped participants achieve their goals but made no impact on ADL or QoL.[167] The '*Journeying through Dementia*' trial of occupational therapy showed no benefit.[168] A consensus is emerging that these interventions do not improve ADL compared with no intervention. The FINALEX intervention was substantially more intensive than the others, which might explain a difference.

Implication for practice and lessons learnt

We showed that a moderate to high-intensity exercise based and functional activity-orientated therapy programme for people with mild dementia or MCI did not maintain independence in ADL or convincingly demonstrate any other health gains. Efforts to enable self-directed activity through use of behaviour change theories were unsuccessful, thwarted by cognitive and physical difficulties. Due to pandemic disruption, uncertainty remains over these conclusions.

It is unlikely that a public health service would be able to deliver an intervention much more intensive than PrAISED. Intensive exercise and functional activity training is unlikely to produce health gain in terms of ADL, physical activity, cognition, mood or QoL. As such, it should not be commissioned, but we highlight some caution in interpretation. The COVID-19 pandemic may have been more disruptive than we have accounted for, and we may have (inadvertently) recruited a socially advantaged group of participants to the trial who were less able to benefit from intervention. Or we may have been unable to measure the things that participants valued from PrAISED.

We add to accumulating evidence that intervention to prevent cognitive or functional decline in early dementia or MCI is ineffective. So far, drug therapies, cognitive stimulation, exercise and rehabilitation therapies have, at best, a small impact on functional activities and QoL and do not appear to change the course of the disease.

Health policy values brief and self-directed interventions, as they are cheaper and can be deployed at scale. The process evaluation suggested that this is unrealistic for people living with dementia, who could, however, engage well in professionally supported therapy. The role of family carers was complex, but it is unlikely that they could replicate what was delivered by professional staff.

We need to think again about how to support people with dementia to live well with the condition. A more supportive approach (drawing from palliative care) may be required. Healthcare interventions should focus on solving practical problems and crises. We should emphasise supporting the person with dementia to reformulate their situation (making the best of a difficult situation, valuing retained abilities and assets), make choices and plan for the future, minimising the burden of intervention or activities, trying to maintain inclusion and occupation, and providing psychological and emotional support. The value of therapeutic relationships may be underappreciated. This may go beyond what might be expected from befriending, counselling or social prescribing. Restoration of 'independence' in activities may be unrealistic; instead, 'adapted' or 'supported' intervention may be more achievable.[169] We need outcome measures that reflect this. Exercise and physical activities should be promoted for enjoyment, occupation and inclusion, and in the context of enhancing relationships. A focus on preventing decline risks 'victim-blaming' when inevitable deterioration occurs.

Recommendations for future research

1. In an ideal world, the PrAISED RCT should be repeated at a time without pandemic restrictions.
2. We need work on characterising, reviewing and testing a broader range of 'psychosocial' outcomes and using them in intervention studies.
3. We need to identify and test alternative approaches to risk reduction and ability maintenance in dementia. The relative ineffectiveness of lifestyle and rehabilitative interventions in changing cognition and function justifies on-going efforts to pursue 'disease modifying' pharmaceutical research.
4. We need to identify and test alternative approaches to support and manage problems associated with inevitable progression and decline in dementia. Alongside this, we require public health, policy or philosophical research on the scope of health care, and the extent to which biomedical outcomes should be prioritised in chronic conditions such as dementia or frailty.
5. We must question the role of conventional RCTs in evaluating complex interventions for progressive conditions.[170–172] While valuable for excluding bias and defining causal certainty, RCTs were designed for simple interventions, usually drugs, and simple or single outcomes, such as occurrence of a disease or mortality. Frail older people

are complex; they are heterogeneous, and comorbidities are common. Interventions are complex, comparators are active, and outcomes are multiple and broad, stretching across physical, functional, psychological and social domains. It is difficult to define universal criteria for success (outcomes may differ between individuals, depending on their individual characteristics and priorities), or to exclude benefits for subgroups, in adequately powered analyses. Realist evaluation (asking 'what works, for whom, under what circumstances, and why?') has been developed to accommodate problems such as these. Comprehensive realist studies can become very large and unwieldy (as there are thousands of potential CMOc to consider), results are less simple, require more interpretation and therefore less easy to use to inform health policy. However, RCTs risk systematically disadvantaging certain populations (including older people, people living with dementia or who are dying) and interventions (rehabilitation, mental health and palliative). These are fundamental questions about the methodology of evaluation, especially in progressive conditions and towards the end of life, where a model of 'supported decline' may be more appropriate than cure or reversal of impairments or problems. 'Supportive' models of care drawing on mental health and palliative care should be considered.[173]

6. Including a wider range of ethnicities and people from less-advantaged socioeconomic groups will require specific design and provision. Current advice on recruitment of ethnic minorities suggests that approach has to come from a clinician or researcher of the same ethnicity, and to actively engage community groups and representatives. This will require specific resourcing.

Conclusions

We delivered an ambitious programme of research to address questions about an important problem: 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 as about as intensive as it would be possible to deliver in the UK health and cultural context. Despite a very positive reception by participants, we measured no benefits from the programme. Our RCT was interrupted by the COVID-19 pandemic, and we were frustrated by epistemological problems, which leave persisting uncertainties about whether a PrAISED-like intervention might be beneficial. However, our findings suggest that a more 'supportive' approach to health care may be appropriate after a diagnosis of dementia, helping to manage problems associated with inevitable functional decline, rather than trying to change the course of disease or to maintain abilities. We assembled substantial new learning in intervention design, training and supporting therapists, behaviour change models in dementia, PPIE, and in process, realist and economic evaluation.

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Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

All studies, and amendments, were approved by the Yorkshire and the Humber Leeds-Bradford REC (18/YH/0059, 1 March 2018).

Information governance statement

Nottingham University Hospitals NHS Trust is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

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Disclosure of interests

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Publications

Cross-cutting

Harwood RH, van der Wardt V, Goldberg SE, Kearney FC, Logan P, Hood-Moore V, *et al*. A development study and randomised feasibility trial of a tailored intervention to improve activity and reduce falls in older adults with mild cognitive impairment and mild dementia. *Pilot Feasibility Stud* 2018;**4**:49. https://doi.org/10.1186/s40814-018-0239-y

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Appendix 1 Summaries of unpublished papers

Adams EJ, Burgon C, Lock J, Smith H, Vickers R, Tucker R, *et al*. Implementation of the PrAISED (Promoting Activity, Independence and Stability in Early Dementia) intervention in practice in England: a mixed methods study.

The full paper is available at:

https://doi.org/10.1101/2023.05.24.23289730

Background

There is a paucity of evidence relating to the implementation of dementia care. The PrAISED intervention is a newly developed 12-month, home-based, individually tailored rehabilitation programme, delivered by therapists and RSWs, with a focus on strength, balance, physical activity and ADL, which has been tested in a RCT. The aim of this study was to identify what is required to implement PrAISED, or similar interventions, in a 'real-world' setting in routine clinical practice.

Methods

A shortened 6-month version of PrAISED was delivered as a pilot service in one NHS organisation in England. Adaptations were made to intervention processes, including changes to the eligibility criteria, referral processes, patient clinical assessments, visit schedules and visit content to facilitate the delivery of PrAISED as a service instead of as part of a research study. Patient characteristics demographics and the number and duration of visits were recorded by intervention delivery staff. These quantitative data were explored using descriptive statistics. Semistructured interviews were conducted with seven members of staff delivering the PrAISED service (two managers, five delivery staff) and eight members of staff from other sites involved in the PrAISED RCT (four managers, four delivery staff). The CFIR was used to inform interview guides and conduct a codebook thematic analysis.

Results

Between April and November 2022, 11 patients (54.5% male; mean age 78; 90.9% White British) were referred to, and participated in, the service. Patients received on average 20.9 visits (mean duration 82.1 minutes). Adaptations were made to intervention processes, including changes to the eligibility criteria, referral processes, patient clinical assessments, visit schedules and visit content. Five themes were identified from interviews relating to the pilot service (pilot service staff only): operational processes; workforce capacity; referral; intervention delivery and patient impact. A further six themes were identified regarding the wider implementation of dementia therapy programmes from interviews with both pilot service and RCT intervention staff: the need for support post dementia diagnosis; acceptability; effective delivery; reach/referral; intervention design and adaptability; and intervention materials and training.

Commentary

We found it was feasible to deliver a 6-month PrAISED intervention as a clinical service with some adaptations, including removal of the research inclusion criteria and replacing them with referral criteria, and removal of research processes (e.g. replacing the patient information sheet with a service leaflet) to make it suitable for service delivery. The shortened duration of the intervention impacted on intervention delivery (increased flexibility with the number of visits, and some changes in session content), which may have affected the fidelity and impact of the intervention.

Themes aligned to the CFIR and have implications for the future implementation of the PrAISED intervention and other similar dementia care interventions in routine clinical practice. In brief, these include the need for: patient support and preventative interventions immediately post dementia diagnosis; funding to establish and implement interventions; leadership and management, including ‘champions’ who can promote dementia care across organisations and the wider healthcare system; time to establish operational processes and embed the intervention into organisational pathways; time to engage relevant staff with wide-ranging personal and clinical skills, provide staff training and establish collaborative working relationships; development of intervention resources and processes (including access to patient medical records), and identification of local services and activities which can support intervention delivery; referral criteria to be established along with referral procedures for suitable patients, and referral staff to be trained on an ongoing basis; and, ensuring interventions can be adapted and delivered flexibly to meet the needs of delivery staff and patients while maintaining fidelity to the original intervention where possible. These are discussed in more detail below.

Support post dementia diagnosis

Our study confirms there is a gap in support for patients immediately post dementia diagnosis. This has been reported previously and exists despite the policy focus on dementia. While the gap may partially be due to lack of infrastructure, and capacity and capability in services, should these infrastructure and resource issues be resolved, PrAISED or a similar intervention could fill this need for support by intervening early and providing a holistic and preventive approach for promoting physical and mental health in dementia patients.

Funding, leadership and operational processes

In order to establish and deliver PrAISED or similar dementia care interventions in current UK healthcare systems, funding will be needed with a substantial initial investment to establish resources and staffing for the intervention. There is uncertainty as to how interventions like this could be funded, which will be a major barrier to intervention implementation and scale-up. A ‘champion’ is needed to promote dementia care interventions and provide leadership and management across organisations and the wider healthcare system. Evidence suggests there is an association between the use of champions and increased use of healthcare innovations by organisations, and that leadership and management support facilitates implementation of dementia care. To facilitate the effective implementation of any new dementia care intervention, and before commencing service delivery, time is needed to establish operational processes (which may take longer than the processes which need to be put in place for research studies), to identify how best to embed the intervention into organisational pathways, to engage relevant personnel and intervention staff (for referral and delivery) and establish working relationships, and to provide staff training.

Staff skills, intervention training and resources

Findings from this study suggest that staff delivering PrAISED or similar dementia care interventions need to have experience of working with patients with dementia along with wide-ranging personal and clinical skills. Further investigation is required to determine if other professionals, for example, those working in the sport and exercise industry, could play a role in delivering PrAISED or similar interventions. The staff need to have capacity to deliver the intervention and be able to work collaboratively as part of a team. Teamwork is essential for effective intervention delivery, and this is known to be important for providing patient care. Intervention-specific training is needed for staff referring to any new service as well as those delivering the service; it is not clear who would provide this training, and this requires further exploration. It has been noted that the time and support needed for staff to gain experience and confidence in delivering a new intervention should not be underestimated. Resources such as training materials, an intervention manual, a patient file and equipment are important for intervention delivery, along with having access to patients’ clinical records, so those delivering the intervention are aware of patients’ medical history, their wider needs and any ongoing support being provided by other services. In addition, therapist knowledge is important for identifying local services and activities to support intervention delivery and sustainability of dementia care.

Patient eligibility and referral

The timing of referral to the PrAISED intervention at the point of diagnosis meant that some of the patients referred to PrAISED were still physically very well and able. Typically, they would not be seen in normal services until their disease had progressed, they had deteriorated and required assistance. However, as noted above, there is a clear need for interventions immediately post diagnosis as a prevention strategy and to support patients at this time, regardless of their physical status. Commissioning preventative interventions, such as PrAISED, for patients with dementia at the time of their diagnosis requires a shift in focus for healthcare services to facilitate access to funding and delivery of interventions of this type. While the NHS Long Term Plan highlights the contribution the NHS will make to prevention activities, it may take some time for this healthcare transformation to be realised.

There were challenges in receiving referrals to the PrAISED pilot service, and this has been noted in other similar studies. Referral pathways need further investigation to increase the number and diversity of patients referred to dementia care services like PrAISED. Ethnic and socioeconomic diversity in PrAISED was limited, and research has shown there are substantial barriers to engaging in dementia health care, rehabilitation and research for some ethnic groups. Options for increasing referrals might include considering whether staff in Memory Assessment Services (MAS) have capacity to undertake referrals to other services alongside their other activities and how this could be managed, and broadening out points of referral, for example, to GPs, memory clinics, falls clinics, day centres or self-referral. The timing of referrals to best support patient needs also needs to be considered. Offering flexibility in the timing of when a patient starts a dementia care intervention may help to address patient preferences for when they most need the support.

Intervention design and fidelity

Home-based dementia care interventions such as PrAISED may help to address inequalities in access to healthcare services for some population groups, as well as facilitating the assessment of patients with dementia and supporting them in their everyday environment. The shortened duration of the pilot PrAISED intervention (due to project timelines rather than a desire to change the 12-month duration of the intervention tested in the RCT) impacted on intervention delivery. There was increased flexibility with regard to intervention delivery, but there was a reduced number of visits, and there were some changes in session content due to having less time and fewer weeks to work with patients. The changes included more focus on risk management, provision of written materials and signposting or referral to other activities and services, prioritising goals, and there was reduced time for tapering therapists' involvement. The duration of any intervention offered in clinical practice would ideally be long enough to allow time to effectively work with patients and enable them to achieve their goals, and deliver the intervention activities as planned, with flexibility for delivering visits and adapting the intervention to patient needs. Balancing intervention adaptation with intervention fidelity remains a challenge in health promotion and prevention, but using adaptable designs, rather than designs with strictly defined fidelity criteria, are thought to be more sustainable and more likely to have public health impact.

Strengths and limitations

This study included a 'first attempt' at delivering the PrAISED intervention as a service in practice. It adds to a paucity of data regarding the implementation of interventions for patients with dementia and provides insight as to what may be required to deliver an evidence-based dementia rehabilitation intervention in routine clinical practice. The pilot service was delivered by an organisation which was involved in the RCT evaluating PrAISED, and, therefore, they may have already been bought-in to the intervention, have staff and systems in place and be familiar with intervention delivery. While this facilitated intervention implementation in the pilot service, there will be organisational barriers to delivering PrAISED in organisations who are completely new to the intervention. The length of the pilot intervention was constrained by the end date of the PrAISED study, which may have affected fidelity. Many interviewees discussed the difficulties of delivering this shorter intervention to patients; however, this may be more reflective of what could be feasibly funded and delivered in NHS services. Given the short duration of the study, the available funding, and the focus on implementation of the intervention, we did not assess the impact of the intervention on patient cognitive and physical outcomes. A future hybrid effectiveness-implementation study is needed to explore this further. Staff who may have been less enthusiastic or motivated to deliver the PrAISED intervention may have been less likely to participate in the interviews.

Conclusion

There is a need for interventions like PrAISED to fill a gap in support immediately post dementia diagnosis. It was possible to deliver a shortened 6-month version of PrAISED as a service in practice, but adaptations were required to deliver the intervention as a service instead of research study, and within the shortened time frame; and referrals were fewer than expected. Future implementation of PrAISED or similar dementia care interventions will require attention to identifying intervention funding, leadership and management, time to establish operational processes, the skills and experience of intervention deliverers, providing training and resources to support intervention delivery, patient eligibility and referral processes, and the duration and components of the intervention. Future research might include a hybrid effectiveness-implementation study to explore these issues further, to examine intervention adaptation and fidelity in practice and to assess the impact on patient outcomes to increase the evidence base for the implementation and effectiveness of dementia care interventions in practice.

Appendix 2 Summaries of unpublished papers

Bajwa R, Howe J, Agbonmwandolor JO, Cowley A, Adams EJ, Goldberg SE, Harwood RH. Exploring the diversity of participants with dementia taking part in research: a mixed methods study.

The full paper is available at:

https://doi.org/10.1101/2023.09.06.23295133

Background

Older adults from Black and South Asian communities have a higher risk for dementia due to an increased prevalence of dementia-specific risk factors, such as hypertension, diabetes and heart disease. Deprivation has also been linked to an increased risk of dementia. Ethnic minority and lower socioeconomic groups are under-represented in dementia research. The aim of this study was to explore factors influencing diversity in dementia and rehabilitation research within the context of the PrAISED RCT.

Methods

We conducted an exploratory sequential mixed-methods study to explore disparities in socioeconomic and ethnic diversity between the PrAISED RCT population and recruitment pathways used in one study site (Nottinghamshire) and compared these with regional and national data. We aimed to collate and summarise data available on ethnicity and deprivation for recruitment/referral pathways (Nottinghamshire site) and the PrAISED cohort (all sites). Additionally, we interviewed HCPs (n = 2), researchers (n = 2) and members of Black and South Asian communities (n = 4) to explore barriers to participating in research for people with dementia.

Results

Under 2% of the overall PrAISED RCT sample (across all sites) were from a non-White ethnic minority background and a third of participants lived in areas with the least deprivation. Referrals to memory assessment services in Nottinghamshire included people from diverse socioeconomic backgrounds, with 7.3% being from non-White ethnic minority communities. Through interviews, several barriers to health care, research and rehabilitation were identified. Healthcare barriers included lack of awareness of dementia, mistrust, stigma, fear, and lack of culturally appropriate services. Research barriers included recruitment routes, awareness of research, language, and recruiter beliefs. Barriers to rehabilitation research included a lack of use of culturally appropriate language, more culturally specific barriers and lack of representation.

Commentary

The findings from this study identified that older adults living with dementia from ethnic minority groups and in areas of deprivation were under-represented in the PrAISED RCT. In the trial under 2% (7/365) of the population were from a non-White ethnic minority group compared to 18% in the general population in England. Additionally, nearly a third of participants (104/365) were living in a neighbourhood in England that was within the 10th (least deprived) Index of Multiple Deprivation (IMD) decile. For the Nottinghamshire site specifically, although the inclusion of participants from ethnic minority communities demonstrated better representation (6/119), nearly half of the participants recruited within Nottinghamshire (50/119) were from an area within the 10th (least deprived) IMD decile, and there was a lack of socioeconomic variation.

From the qualitative findings, the identified communities had many barriers to accessing research. Firstly, due to a reliance on using health care as a route to recruitment, a lack of engagement in healthcare services had similar repercussions for research. There was a distrust of healthcare services, concerns about the stigma of a dementia diagnosis and a lack of culturally sensitivity within some healthcare services that may be leading to a lack of engagement in Memory Assessment Services. Restrictions to recruitment based on language also purported to be excluding otherwise suitable candidates which would widen the diversity within recruitment samples. Accessing rehabilitation research had further barriers related to feelings of a lack of representation and interventions that accommodate cultural requirements, particularly for South Asian communities.

The limited inclusion of people from Black and South Asian minority groups and diverse socioeconomic background is not unique to the PrAISED RCT, with studies such as the DAPA trial and FINALEX also recruiting largely White populations. Systematic reviews exploring representation of ethnic groups in dementia trials also found that non-White ethnic minority groups were under-represented with one review reporting on average 94.7% of study populations in drug trials for Alzheimer’s disease between 2001 and 2019 were White. Under-representation of diverse groups is not unique to dementia research, with other areas of medical research highlighting the historic under-representation and need for increasing access to research for minority groups.

When exploring ethnic and socioeconomic diversity within the PrAISED recruitment pathways at the Nottinghamshire site, we were only able to access data on ethnicity and deprivation from the MAS pathway. GP surgeries involved in screening for PrAISED recruitment did not routinely collect ethnicity data from patients during the registration process. We also were unable to access data on ethnicity and socioeconomic status volunteers registered on the NIHR JDR register in Nottinghamshire. Though a recent report by the Alzheimer’s Society and a study from JDR have identified that areas of deprivation and minority communities are under-represented on the JDR. These findings highlight a bigger challenge around data recording and access. Previous work has highlighted that ethnicity is not well recorded in research. Without routinely recording this data to enable monitoring and uptake of dementia services and participation in research by marginalised groups, it is a challenge to ascertain which groups are being excluded, at what stage and where more targeted engagement strategies are required.

This study echoed similar findings into the experience of minority ethnic communities accessing health care and research for people with dementia. A meta-analysis of 33 studies identified that within Western society those from a minority ethnic background are diagnosed at a later stage and less likely to access health care and participate in research. The barriers identified to recruitment are similar to those previously reported in a systematic review, which also highlighted barriers related to health services, research processes as well as practical and community related barriers. Differences between cultural understanding of dementia, shame, stigma and negative experiences of healthcare services have previously been identified as barriers to people from minority ethnic communities accessing diagnostic services. Previous work has also discussed the issues of stigma relating to dementia for ethnic minority groups, especially within South Asian communities, and the impact of this is not only for the individual but also for their family unit.

This study also found barriers around lack of trust and culturally aware services. Our interviewees highlighted the lack of culturally inclusive healthcare organisations and the need for culturally aware staff to be able to cater for the needs of diverse communities. The issues around trust of HCPs and services are not unique to dementia services. Trust can be difficult to build in intercultural healthcare and research practices due to historic cases of unethical research practices in the Black community, personal negative experiences of health care, and a fragmented, discontinuous model of healthcare delivery.

This study highlighted research-specific barriers to participation, including lack of awareness of what research is, what it involves and what the benefits are for the individuals. The requirement to speak English to participate and the style of language used in research documentation (such as information and consent forms) can be limiting for older adults from minority communities, where literacy skills may be poor or where English may not be their spoken language. Additionally, for those who do speak English, research language may involve technical terms or jargon, which may put people off from taking part. Research methods and processes may also hinder inclusion, as current systems for study document approvals are rigid and time-consuming. Recruitment routes used in research, such as recruiting from healthcare services, is another barrier. Previous work has shown that older adults with memory problems from ethnic minority and lower socioeconomic groups do not access healthcare services until later in the disease progression, or may only access services when in crisis, at which point they may not meet strict eligibility criteria. A qualitative systematic review exploring recruitment and methodological issues in dementia research in ethnic minority communities reported similar themes around the use of language and recruitment strategies being barriers to participation.

Another noteworthy subtheme relating to research barriers was the recruiter's beliefs and priorities. If the recruiter or HCP were not enthusiastic about the study, this may have deterred patients. Additionally, recruiters and HCPs may act as gatekeepers prioritising protection of patients they may perceive as in a state of high stress, therefore limiting their access to recruitment materials. The National Standards for Public Involvement identify that we should be offering inclusive opportunities for people to engage in research.

To date, there has been little exploration around the barriers to rehabilitation research for older adults with memory problems from ethnic minority communities and diverse socioeconomic groups. We found several barriers to rehabilitation research around the lack of culturally appropriate language; consideration for specific cultural barriers, such as traditional dress, which could impact an individual's ability to take part in particular rehabilitation activities; and the lack of representation of staff delivering rehabilitation programmes. These findings are in line with previous work, which has highlighted cultural barriers to physical activity and exercise participation. Two systematic reviews of barriers and facilitators to physical activity in ethnic minority groups in the UK found that religion may facilitate participation in physical activity, but religious fatalism may be a barrier. Mixed gender exercise classes and dressing in exercise-type clothing may also not be socially acceptable in some cultures. The lack of culturally aware spaces for physical activity was another key barrier to participation. Researchers, clinicians and funders should look to address these barriers when designing new rehabilitation interventions to ensure that future rehabilitation research is accessible and inclusive.

Limitations

Previous research has shown that people from ethnic minority and lower socioeconomic background often access service at a later stage or crisis point and often experiences challenges and delays during the diagnosis process. We did not collect data from memory services on the dementia severity of patients who received a diagnosis. Including these data would be useful to understand at what stage of dementia people from minority groups are presenting in the health service and could explain why these groups may be under-represented in the PrAISED RCT which aimed to recruit older adults with MCI and mild dementia.

Challenges around data recording and access meant we could not fully explore diversity present in all recruitment pathways for PrAISED in Nottinghamshire, thus making it difficult to ascertain where services and research become inaccessible for ethnic minority groups and those from diverse socioeconomic backgrounds. GP practices reported that they did not collect data related to ethnic group, meaning we were not able to assess these data. Future work needs to look at how data capture of diverse characteristics can be improved to ensure that research and services in dementia and wider can monitor access and uptake of healthcare services and research and improve engagement with underserved communities at a local and national level.

The interview sample size was small. We spoke with three interviewees from the South Asian community and one participant from the Black Caribbean community. It is important to note that there are a lot of different communities within Black and South Asian groups, and though there are common barriers experienced across communities, there may also be unique community-specific barriers which we did not identify. These interviewees were identified through existing patient and public involvement networks and therefore already had some knowledge of research processes, this may have added to their understanding of the topic; however, their opinions may be different to members of their community with less understanding. Future work should look to examine unique challenges for each community in more detail.

The research interviewees representing MAS, for example, were based within areas of the county where there was less diversity and had received a positive reception to discussing research participation to people with dementia. Attempts were made to recruit representative of more deprived areas of Nottinghamshire; however, there were no established connections with these communities. It was identified that recruitment would have required the researchers to have built community relationships and developed trusting partnerships with community organisations to develop a recruitment pathway, and this was not possible within the time frame of the study.

A series of recommendations for dementia research and clinical research more generally are outlined below to improve the diversity of ethnic minorities and lower socioeconomic groups in research. Improving equity, diversity and inclusion of older adults with memory problems from historically marginalised communities in dementia services and research is important to ensure that all those affected by dementia can live well with dementia.

Recommendations

Based on the findings, some recommendations are proposed for services and research both for people with dementia and the wider population:

1. Increase representation and develop a culturally competent workforce. Funders and universities should invest in developing opportunities for diversity in their workforce to enable research teams to look similar to the target participants and speak their languages. Developing workforce skills in cultural competence will enable participants to feel understood and assured that their needs will be met.
2. Build trust between communities. Investment is required from universities and healthcare services to provide stable resources and staff to build these relationships. Mistrust in minority communities is a key barrier to service access. To build trust, HCPs and researchers need to adopt a non-judgemental approach, awareness and acceptance of other’s cultures. Additionally, improving awareness of dementia, related services and research available to these groups will also aid inclusion and access.
3. Provide accessible information, such as videos with study information in addition to written participant information sheets. Information sheets and consent forms need to be shorter and simpler. This may be helpful for groups where English may not be their first language, or for groups who may have a lower level of literacy. Translate information into different languages for those who do not speak English and ensure the style of language used is in line with the style used by different groups in their day-to-day interactions. It is important to ensure that the information presented uses culturally acceptable terms.
4. Develop recruitment strategies. These need to be flexible, rather than just clinical or service-based, researchers should go out into the community and settings that are regularly attended by ethnic minority groups. For instance, the radio may be an effective strategy to advertise research and disseminate findings to older adults from Black and South Asian communities. Targeted promotion may be a useful strategy to increase inclusion and access for certain groups that may be consistently under-represented.
5. Provide renumeration, particularly for lower socioeconomic groups. This may improve the accessibility and, subsequently, inclusion of these groups in research. Potential participants from lower socioeconomic groups may face the dilemma of lost earnings and being out of pocket if they take the time to participate in research, covering expenses, and lost earnings can improve access for these groups.
6. Increase flexibility within research methods and processes. Current process for approvals for studies and related documents are often rigid and can take a long time. Working with research governance bodies and including stakeholders from multiple communities, a more dynamic research processes need to be developed so that research can be adapted quickly to meet the needs of different communities.

Conclusions

Participants recruited to the PrAISED RCT were disproportionately White and socioeconomically privileged. Data recording and access around ethnicity is inconsistent, making it difficult to ascertain at which point services and research become inaccessible for people from underserved communities. This study has highlighted the disparity between diversity in the community, in referrals to services and in diversity in research studies, drawing on the PrAISED research programme as an example. Several barriers were identified at different points in the healthcare and research systems for Black and South Asian ethnic minority groups, focusing on trust in health services and research, and doubts about the diagnosis of dementia. Researchers need to work with ethnic minority and socioeconomic diverse groups to explore common and community-specific barriers to access, and inclusion in dementia services and research. In addition to this, future work should include working closely with underserved communities to develop and implement actions to address barriers.

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