

Title: A systematic review of process evaluations for psychosocial interventions designed to improve the wellbeing and quality of life of community-dwelling people with dementia and their carers.

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ABSTRACT

Background: Psychosocial interventions improve the wellbeing and quality of life of People Living with Dementia (PLWD) and their family carers; but due to their complexity it can be challenging to identify mechanisms of action. We reviewed process evaluations that have sought to elucidate how these interventions work, to inform their implementation.

Method: We systematically reviewed process evaluations of studies evaluating psychosocial interventions for PLWD in their own home and/or their family carers. We rated study quality using the Mixed Methods Appraisal Tool (MMAT). We described, with reference to Medical Research Council (2015) process evaluation guidance, how implementation, mechanisms of impact and contextual factors were investigated; and describe commonalities in the mechanisms of action identified across studies.

Results: 24 included studies evaluated the processes of 22 interventions. These studies collectively applied five frameworks; almost all frameworks' advised evaluations were theory-based and used mixed-methods analyses, but only 5/24 evaluation designs were informed by the intervention theory and 8/24 used mixed methods. 8/24 evaluations considered contextual factors in their design, though 20/24 cited contextual factors in findings.

Interventions were more successful where PLWD were motivated and aware of potential benefits, and when carers could support engagement and were themselves supported by the intervention. How the intervention aligned with participants' current needs and stage of dementia were key influencing factors.

Conclusion: Knowing how interventions can influence change for community-dwelling people with dementia and their family carers will improve translation of trial findings into practice. Robust, theory-driven process evaluations can enable this.

KEYWORDS

Process evaluation, dementia, wellbeing, systematic review, psychosocial interventions.

KEY POINTS

- Interventions for people living with dementia at home and their family carers were more successful where the participants were motivated and aware of potential benefits
- How the intervention aligned with participant's current needs and stage of dementia were key influencing contextual factors
- Key influencing mechanisms of impact were provision of support for the family carer, whether through the facilitator or through peers.
- Influencing implementation factors related to the quality of content and flexibility of delivery of intervention components.

FUNDING

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DECLARATIONS OF INTEREST

Declarations of interest: none

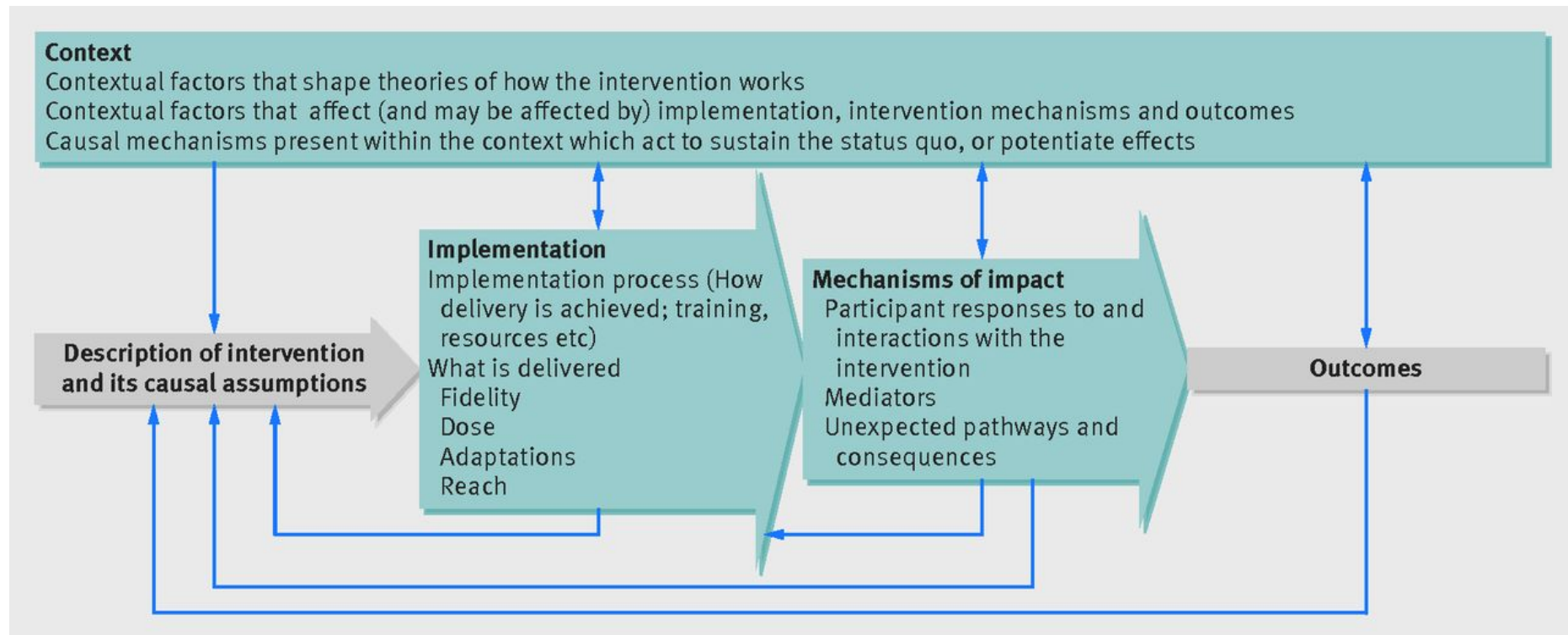
1. Introduction

Dementia is a syndrome involving cognitive decline beyond that expected from biological aging.¹ An estimated 850,000 UK people live with dementia, with numbers predicted to increase to over 1.2 million by 2030.² UK Government policy advocates supporting people living with dementia (PLWD) to retain their independence at home through personalised support and adaptations.³ In the absence of a cure, psychosocial interventions—informed by the bio-psycho-social model of dementia and a person-centred approach to account for personal, social and emotional needs—are valuable in contributing to the wellbeing and quality of life of PLWD.⁴ These interventions are complex with multiple interacting components.⁵ Randomised controlled trials (RCT) are regarded as the 'gold standard' for measuring the effectiveness of complex psychosocial interventions.⁵ To understand *how* (in addition to *if*) an intervention influences change, RCTs can incorporate a process evaluation,⁵ to explore how complex interventions generate outcomes, and why they may work within some contexts, for some populations, but not others.⁶ They examine how an intervention influences change (testing causal assumptions drawn from intervention theory), and if it was delivered as planned (considering delivery, implementation processes, dose and reach).⁶

Medical Research Council (MRC) guidance published in 2015⁵ recommends that the evaluations, are designed around the theory of how the intervention is expected to work (a theory-based approach). Figure 1 shows the key factors that the guidance⁵ recommends process evaluations consider (context, mechanism, and implementation factors).

Figure 1

Key functions of Process Evaluation and relations among them.



Note: From Moore^{5(p2)}

Recent cross-disciplinary systematic reviews^{7,8} have found that the term ‘process evaluation’ is inconsistently used⁷; and that while two thirds of process evaluations cited a theoretical approach, only one quarter were informed by, applied, or tested a theory.⁸

Psychosocial interventions for PLWD are complex: they usually involve both the family carer (henceforth referred to as carer) and the PLWD—often referred to as a dyad— and are multi-model in approach to account for the complexity in how dementia affects lives.

To our knowledge this is the first systematic review analysing process evaluation design and outcomes of psychosocial interventions designed to enhance the wellbeing of community-dwelling people with dementia and their carers. It will inform design of future psychosocial interventions and their associated process evaluations and build understanding of how these interventions influence change for community-dwelling people with dementia and their family carers.

We explored the methods used with reference to the MRC guidance⁵ process evaluation components for implementation, mechanisms of impact and contextual factors (Figure 2). By reviewing the findings of the included studies, we also sought to identify any common factors that influence change for this population.

2. METHOD

We registered the protocol on the Prospective Register of Systematic Reviews (PROSPERO - CRD42020221337).

2.1 Search Strategy

We carried out a primary search on Scopus, then searched PsycINFO, MEDLINE, CINAHL, Web of Science and Cochrane Library with no limit on dates. Key search terms were: (“process evaluation”) AND (Dement* OR Alzheimer*) AND (Random* OR RCT)). We searched references of included studies, ISRCTN and ClinicalTrial.Gov registries and used citation tracking. Searches took place 2 December 2020, repeated on 6 July 2021. Final searches were repeated on 6 September 2022.

2.2 Study inclusion and exclusion criteria

We included studies evaluating interventions that used psychosocial strategies and aimed to improve wellbeing or quality of life of the PLWD or their carer. We included interventions that focused on education, awareness, support, environmental adaptations, behavioural change and/or management. Due to the inconsistencies around the use of the term ‘process evaluation’,⁷ we included all studies evaluating how an eligible intervention worked, irrespective of whether it was termed “process evaluation”. We included primary research studies using qualitative, quantitative, and mixed-methods. We excluded studies that evaluated pharmaceutical agents or were not in English.

2.3 Procedures

Papers identified in searches were stored on Covidence, with duplicates removed. Titles and abstracts were screened by DW to identify studies that met the inclusion criteria; 10% were independently checked by JB. Full texts of potentially eligible articles were assessed for inclusion by DW, with JB independently reviewing a minimum of 20%. All eligible papers were screened for quality using the Mixed Methods Appraisal Tool (MMAT) Version 2018.⁹

2.4 Data extraction

We extracted data from eligible papers, regarding the intervention (see Appendix A) and process evaluation: (1) its aims and how the evaluation was described (whether as a process evaluation); (2) whether authors specified a framework, and which one; (3) whether data collection methods were described as: 'mixed-methods' (and further descriptors used for the type of mixed-methods analysis and how data was integrated), 'qualitative and quantitative', 'qualitative', 'quantitative', or 'not specified', (4) whether the evaluations described the causal pathways or theory, and how this was used in designing the evaluation, (5) We extracted information regarding the components of the intervention processes that were evaluated, and the findings reported, categorised according to the 2015 MRC guidance⁵ description of implementation, mechanisms of impact, and contextual factors (Figure 1 and Appendix A).

2.5 Assessing study quality

We used the Mixed Methods Appraisal Tool (MMAT) Version 2018⁹ to assess study quality. The MMAT is used to appraise study methodological quality by answering 'yes', 'no', or 'can't tell' across a two-part checklist. Part one comprises two screening questions (1) Are there clear research questions? (2) Do the collected data allow to address the research questions? Responding 'no', or 'can't tell' to either question suggests the paper is not an empirical study. Part two rates specific criteria based on the study design, for example qualitative, mixed-methods, or randomised controlled trials.⁹

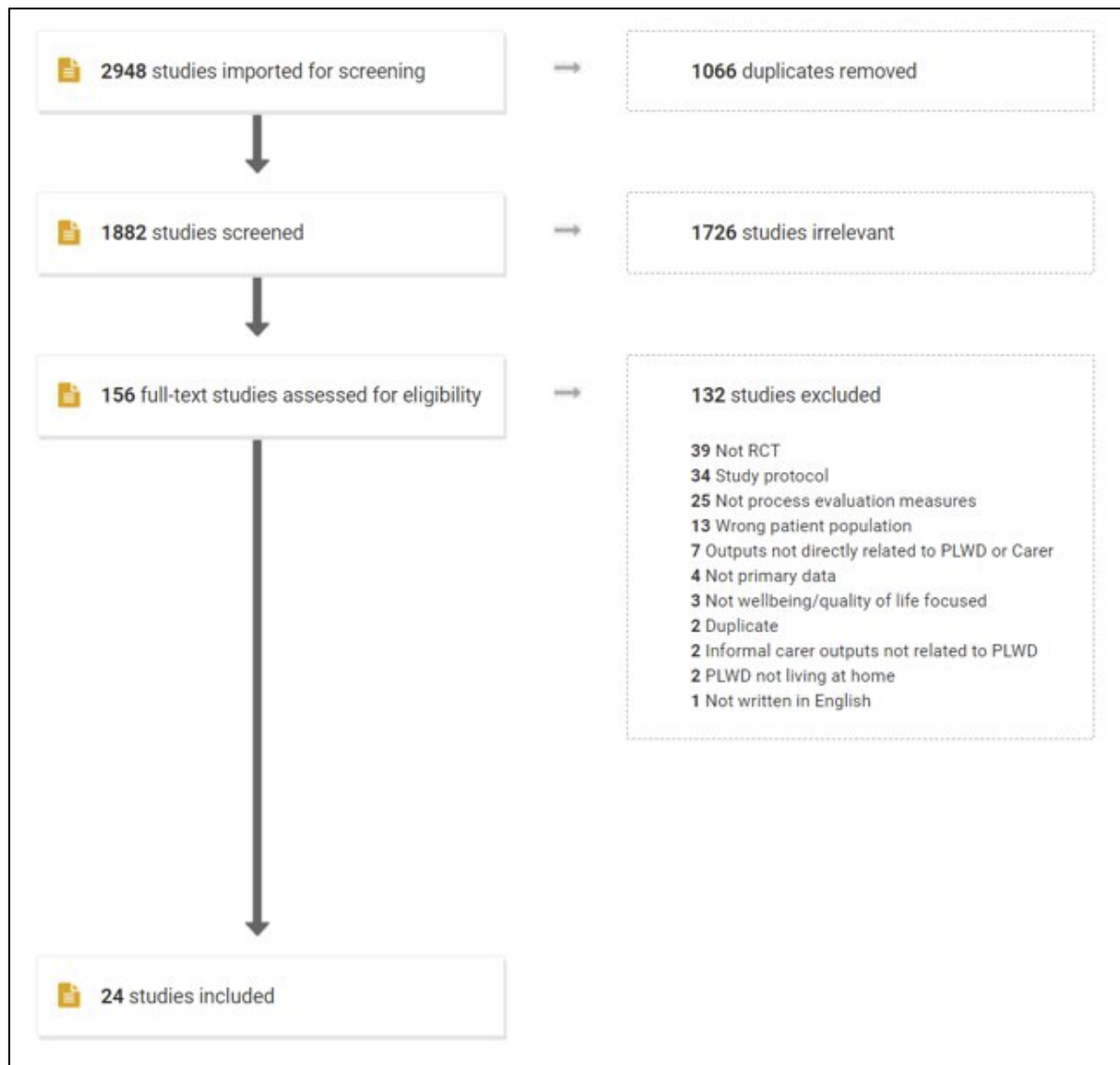
3. RESULTS

3.1 Search strategy results

We included 24 studies evaluating the processes involved in delivering 22 psychosocial interventions. Search strategy results are summarised in Figure 2.

Figure 2

PRISMA diagram



3.2 Study quality

Out of the 24 included studies, eight evaluations¹⁰⁻¹⁷ answered 'yes' to all MMAT sections, indicating a high level of quality. Two evaluations^{18,19} answered no to one question in part two, and 12 evaluations answered no to more than one question in part two, indicating that criteria for high quality rating were not achieved.²⁰⁻³³ Eight of the 13 studies that answered no to more than one question collected both qualitative and quantitative data yet did not define themselves as using a mixed-method design^{20-22,24,26,28,32,33} and were initially assessed under the mixed-methods section, and then reassessed for the quality of both components (qualitative and quantitative). In their reassessment six studies^{20,22,24,26,32,33} answered yes to all sections relating to their qualitative and quantitative components. Two studies^{21,28} answered 'no' or 'can't tell' more than once indicating they did not achieve a high-quality rating for their component parts.

3.3 Summary of interventions evaluated by included studies (see Appendix B)

The interventions evaluated involved: physical activity^{15, 16, 25, 26, 30} or multi-component psychoeducational approaches delivered face-to-face or using blended approaches,^{10-14, 17-19, 21-23, 28,32} or online.^{20,24,27,29,31}

The physical activity-based interventions were delivered in participants' homes, over 6-52 weeks. One involved Tai Chi, to improve PLWD's postural balance.¹⁵ The others provided dyads with multi-component exercise and support activities, to enable social participation,^{25,32} or reduce depressive symptoms,³⁰ or disability.^{16,26}

The multi-component interventions involved individual and group activities for carers, or dyads, in regular sessions over 4 weeks to 18 months, or in one case in a five day residential course for carers.²¹ They targeted carer outcomes: stress and depressive symptoms,¹⁰ self-efficacy,²² or quality of life,²¹ dyadic relationship quality,¹³ or the daily functioning,^{18,23,33} independence,¹² behavioural, cognition or quality of life of the person living with dementia.^{11,17} Some psychoeducation interventions were delivered to professionals, with the aim of improving clients' outcomes; including nurse-led case-management for carers,²⁸ and mental health professionals' training.¹⁹

Psychoeducational online interventions targeted carers and used experience sampling (assessing experiences in the moment) to empower positive experiences,³¹ personalised interactive training to improve self-management and increase social activities,^{20,29} self-management support,²⁷ and use of a social support platform.²⁴

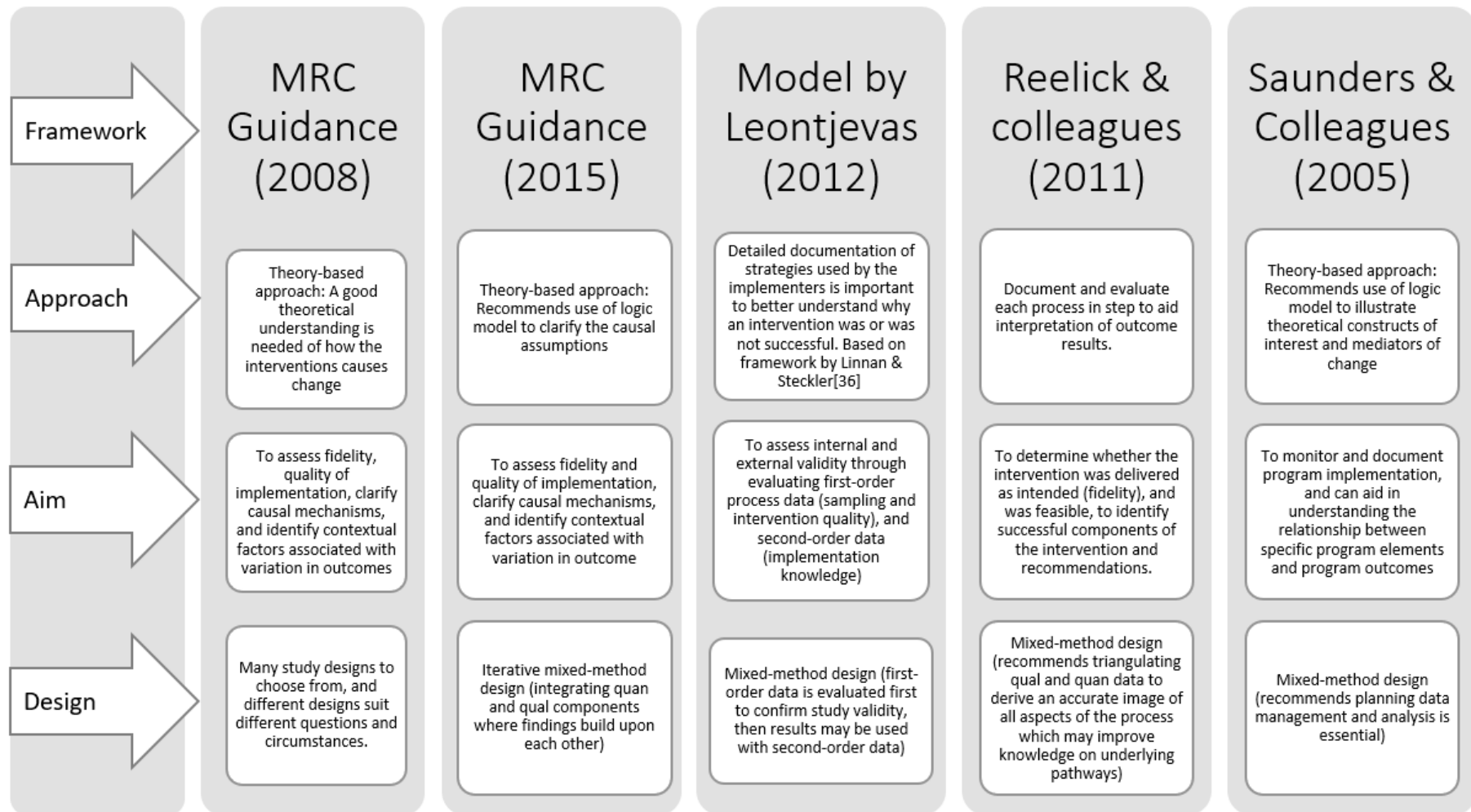
3.4 Evaluation frameworks

16/24 studies^{10-12,18,20-25,27,28,30,31-33} were termed 'process evaluations'. Others investigated how the intervention worked, and from hereon in will be referred to as process evaluations.

14/24 evaluations stated they were using a theoretical framework to shape how the evaluation was organised and run. The approaches, aims and recommended designs for each of the five frameworks used are summarised in Figure 3. Nine included studies used the MRC Guidance; seven^{10,12,14,20,21,23,27} used the MRC process evaluation of complex interventions guidance,⁵ and two^{18,29} the 2008 MRC guidance.³⁴ The other evaluations used models described by previous authors: three papers^{22,24,31} a model from Leontjevas et al,³⁵ one evaluation²⁵ a model by Saunders et al,³⁶ and one evaluation³⁰ a model presented by Reelick et al.³⁷ Six evaluations^{11,13,18,19,28,30} were conducted before the MRC guidance⁵ was published.

Figure 3

An overview of the different frameworks applied.



3.5 Research design

Out of the 24 evaluations, eight^{10,12,23,25,27,29-31} applied a mixed-methods design. Of these, only two specified the type of mixed-methods design including data integration, both of which were rated as being of higher quality, as parallel convergent,¹⁰ and explanatory sequential.¹² Six evaluations^{20-22,24,26,28} described collecting both qualitative and quantitative data but did not specify integration techniques. Six evaluations^{11,13-17} were qualitative studies, all of which were rated as being of higher quality, and two evaluations were quantitative studies.^{18,19}

3.6 Theoretical approach

Intervention theory—defined here as a specific model of behaviour change to explain how the intervention produces change—informed the evaluation design in five included evaluations, all of which were rated as being of higher quality.^{10,11,14,15,17} Two of these theories explain how carer stress can be reduced. In their process evaluation of a caregiver intervention, Gaugler et al¹⁰ adopted family systems theory, and the stress process model. These theories, posit that carers have resources within themselves, their families, and communities they can use to reduce the impact of stress on carer and care recipient wellbeing. Lavoie et al¹¹ based their process evaluation of a carer group support intervention on the Transactional theory of stress and coping, which describes how carers identify stressors and develop coping strategies.

Three evaluations used theories considering how PLWD can engage with and benefit from interventions. Sprange et al¹⁴ used social cognitive theory when designing their evaluation. This theory, which they drew upon in their data analysis, focuses on behavioural change and effective problem solving to promote increased self-management, independence, improved wellbeing, and life satisfaction for PLWD and their carers. Barrodo-Martin et al¹⁵ used self-determination theory (SDT) and self-efficacy theory (SET) to understand factors influencing PLWD adherence to Tai Chi home practise, to develop the topic guide. SDT states that behaviours are sustained if individuals intrinsically enjoy them, and they fulfil needs of autonomy, competence, and relatedness. SET posits individual behaviour results from self-perceived ability to perform it, and outcome expectancies. Leung et al¹⁷ used the theoretical framework of carer involvement in cognition-based interventions for PLWD to derive their topic guide. It posits carer involvement may enhance dyadic mutual understanding, communication, relationship quality and well-being.

Rather than apply the intervention theory to evaluation design or at the analysis stage, Walton et al¹² and Hancox et al²⁶ deductively applied theory to their findings post analysis, to help interpret their findings. For evaluating their intervention feasibility trial, Walton et al¹² used theory-based, systematic methods to map the evaluation findings to the Behaviour Change Wheel framework to develop primary strategies to improve fidelity of, delivery of, and engagement with a future Promoting Independence in Dementia RCT. Similarly, Hancox et al²⁶ applied the Theoretical Domains Framework post analysis to assess barriers and facilitators to engaging with the Promoting Activity, Independence, and Stability in Early Dementia intervention.

None of the 24 included evaluations used a logic model or theory of change to illustrate intervention causal pathways.

3.7 Evaluation aims, components evaluated, and key findings

Table 1

Summary of included evaluations; study, description, evaluation, aim, framework applied, whether informed by theory, design, participants, data collected, and whether the data was integrated.

Study	Evaluation aim	Framework	Informed by theory	Design	Evaluation participants	Qual data collected	Quan data collected	Data integrated
Barrado-Martin¹⁵	Understand what influenced participant adherence	Not specified	Yes	Qual	Dyads	Interviews (n=15)	NA	NA
Beentjes²⁰	Evaluating the feasibility of the intervention and research protocol.	MRC Guidance (2015)	No	Quan & qual	Dyads & other stakeholders	Interviews with intervention (n=10), control (n=10) participants & stakeholders.	Ordinal questions during interview	No
Birkenhager-Gillesse²¹	Estimate the internal and external validity	MRC Guidance (2015)	No	Not specified	Dyads	Feedback meeting data and follow-up meetings (n=49 intervention arm)	Recruitment, reach, and attrition data, training logbook,	Unclear
Boots²²	Determine internal and external validity	Leontjevas (2012).	No	Quan & qual	Carer of PLWD & professionals delivering intervention	focus group & questionnaire (n=10 professionals), participant semi-structured interviews (n=49)	Sampling quality (recruitment, informed consent, allocation, reach), and Implementation (components received)	No
Chester²³	Identify how delivery components are associated with outcomes.	MRC Guidance (2015)	No	Mixed-methods	Dyads & interventionists	Practitioner interviews (n=5)	Analysis of intervention records (delivery and participation factors)	No
Clare³³	To address the process of goal-setting and the process of therapy	Not specified	No	Qual & Quan	Dyads	Focus group with therapists (n=6), interviews with participants (n=25) and carers (n=26)	Comparison of goal attainment scaling ratings, flexibility in delivery, therapy logs.	No
Dam²⁴	Evaluate the internal and external validity	Leontjevas (2012).	No	Qual & Quan	Carer of PLWD	Semi-structured interview (n=10 intervention-arm)	Sampling (recruitment, consent, allocation, reach), Intervention (feasibility, fidelity)	No
Di Lorito¹⁶	Explore participants experiences of the intervention	Not specified	No	Qual	Dyads	Interviews (n=5 intervention-arm dyads). Therapists (n=5)	NA	NA
Donkers²⁵	Explore why the trial failed.	Saunders & Colleagues (2005)	No	Mixed-methods	Dyads & interventionists	Questionnaire & focus group/interview for	Analysing telephone interviews, medical	No

Study	Evaluation aim	Framework	Informed by theory	Design	Evaluation participants	Qual data collected	Quan data collected	Data integrated
Gaugler¹⁰	Identify how delivery components are associated with outcomes	MRC Guidance (2015)	Yes	Mixed-methods	Carer (adult-child) of PLWD	professionals (n=16), participant interviews (n=5). Open-ended feedback (n=54)	records assessed by predefined checklist, Process and implementation data, context of care, objective and subjective stressors, depressive symptoms.	Yes
Hancox²⁶	Explore what influenced participant adherence	Not specified	No	Not specified	Dyads	Semi-structured interviews (n=20)	adherence from daily exercise diaries	Yes
Huis in het Veld²⁷	Explore what influenced participant adherence	MRC Guidance (2015)	No	Mixed-methods	Carer of PLWD & nurses delivering the intervention	Semi-structured interviews (n=12 carers, & n=4 nurses). Analysis of email contact content (n=27 carers and nurses)	Actual usage of personal email contact, clicks on video links, clicks on e-bulletin, evaluation survey questions	No
Jansen²⁸	Evaluate intervention fidelity and participant satisfaction	Not specified	No	Not specified	Carer of PLWD & interventionists	Semi structured interviews with nurses (n=3)	survey (Carer n=54), hours spent on case management, Care giver's satisfaction.	No
Johannesse n¹³	Explore participants experiences of the intervention	Not specified	No	Qual	Carer of PLWD	Semi-structured interviews (n=20)	NA	NA
Kerkhof²⁹	Evaluate the feasibility, implementation strategy and mechanism of impact	MRC Guidance (2008)	No	Mixed-methods	Dyads	Interviews (control group n=4 PLWD, n=6 Carers control group; intervention-arm n= 6 PLWD, n=7 Carers)	Self-management data, activities participation, self-efficacy, autonomy and QoL, feeling of competence, positive care	No

Study	Evaluation aim	Framework	Informed by theory	Design	Evaluation participants	Qual data collected	Quan data collected	Data integrated
							experiences, recruitment.	
Lavoie¹¹	How delivery components are associated with outcomes	Not specified	Yes	Qual	Carer of PLWD & interventionists	Semi-structured interview with Carer (n=30)	NA	NA
Leung¹⁷	Explore participants experiences of the intervention	Not specified	Yes	Qual	Dyads	Semi-structured interviews (n=23)	NA	NA
Mehling³²	Assess adherence and satisfaction of study components	Not specified	Yes	Quan & Qual	Dyads	Open-ended survey questions (n=29)	Satisfaction survey, participant adherence	No
Prick³⁰	Identify how delivery components are associated with outcomes	Reelick and colleagues (2011)	No	Mixed-methods	Dyads	Semi-structured interviews (n=11), caregiver activity logs, & interviewer reflective logs	Recruitment and selection rate, attrition rate, data completeness	Unclear
Spijker¹⁹	Explore what influenced participant adherence	Not specified	No	Quan	Dyads & interventionists	NA	training and screening data (n=48), carers' depression, sense of competence, distress, PLWD behaviour.	NA
Sprange¹⁴	Explore participants and facilitators experiences of the intervention	MRC Guidance (2015)	Yes	Qual	Dyads & professionals delivering the intervention	Semi-structured interviews with facilitators (n=10), supervisors (n=4), & participants (dyad n=4, PLWD n=11, carers n=6).	NA	NA
Van Knippenberg³¹	Determine internal and external validity	Leontjevas (2012).	No	Mixed-methods	Carer of PLWD & interventionists	Semi-structured interviews (n=20 intervention-arm)	Sampling (Recruitment, randomisation, reach), Intervention fidelity	No
Voigt-Radloff¹⁸	Explore why the trial failed	MRC Guidance (2008)	No	Quan	Dyads & interventionists	NA	Patient data, therapist expertise, intensity of treatment, study design.	NA

Study	Evaluation aim	Framework	Informed by theory	Design	Evaluation participants	Qual data collected	Quan data collected	Data integrated
Walton ¹²	explore fidelity and participant engagement	MRC Guidance (2015)	No	Mixed-methods	Dyads & interventionists	Semi-structured interviews (professionals n=8), PLWD n=7, and carers n=7)	Fidelity and engagement	Yes

The key aims of the included evaluations were to understand factors related to implementation, mechanisms of impact and context (see Figure 1). Several studies explored factors of implementation through the influence of adherence on outcomes,^{15,19,26,27,32} other studies reported intervention feasibility,^{20,29} fidelity and participant engagement/satisfaction,^{12,28,32,33} and to understand why the trial failed.^{18,25}

Factors related to mechanisms of impact were studied through investigating participant responses, mediators and unexpected pathways and consequences. Studies mapped delivery components to outcomes,^{10,11,16,23,30} and explored participants' experiences of the intervention.^{13,14,17,33}

Most studies reported context (anything external that impacts implementation or its effects) to at least some extent. In four studies this was explicit, as they reported internal (intervention-related) and external (sampling-related) validity of the intervention delivery.^{21,22,24,31}

The next section outlines components evaluated and key findings for the included studies.

3.7.1 Multi-component physical activity-based interventions^{15,16,25,26,30,32}

All these studies measured adherence to exercise interventions; common themes were greater adherence in contexts where PLWD were more motivated and aware of potential benefits; and carers were not too burdened to support the intervention (especially when the intervention was online). Interventions that promoted routine, were not too complicated and had clear and helpful supportive materials, for example exercise logs, were associated with greater adherence. In one study, Prick et al³⁰ commented that efforts to recruit those with an interest in exercise may have generated a self-selected group of dyads who were motivated to exercise, explaining their high adherence rates. Putative mechanisms of impact, including increased awareness of benefits of targeted behaviour changes, and experiencing positive effects from the intervention, including pleasure, improved mood, and self-esteem were also related to higher adherence. Donker et al²⁵ used a mixed-methods approach, concluding that a lack of motivation to increase social participation, caregiver burden (also cited as reasons for reach and recruitment difficulties), changing needs of participants, and professionals working across multi-disciplinary teams were key barriers to delivery. Implementation complexity, difficulties on setting attainable goals, and tension caused by evaluating a tailor-made intervention with a fixed study design were cited as reasons why the trial failed. Mehling et al³² found transportation issues to the sessions had a negative impact on class adherence.

Similarly, using solely qualitative methods, Barrado-Martin et al¹⁵ and Hancox et al²⁶ found that adherence was better for those who realised the importance of a routine and attributed progress to their efforts. In the absence of an instructor, good supportive materials improved adherence. Di Lorito et al¹⁶ concluded that an exercise intervention could be successfully delivered through a video-calling platform introduced during the intervention due to COVID-19 restrictions, though this relied on having a carer and invested, enthusiastic, and known therapist.

3.7.2 Psycho-education interventions

3.7.2.1 Face to face and/or blended psycho-education interventions^{10-14,17-19,21-23,28,33}

A key theme across these studies was the importance of stage of dementia as a context; with interventions that could be tailored to the needs of people living with dementia more likely to be used. Johannessen et al¹³ found that a dyadic support intervention might work

better earlier in the dementia illness. Leung et al¹⁷ also referenced stage of dementia as an important context to consider in how a carer-delivered individual cognitive stimulation therapy (iCST) intervention operated. Clare et al³³ noted that participants who had a more recent diagnosis tended to be more motivated to engage in the intervention.

For interventions targeting family carers, flexibility of delivery and a supportive environment were key. For carer computer-based interventions, computer literacy was key. Lavoie et al¹¹ considered how, mutual reinforcement of support and educational processes (carers being supported to use learnt strategies), was an important mechanism of impact in a carer coping strategy intervention. Gaugler et al¹⁰ evaluated carer counselling and group support, found the participants preferred to save up their counselling sessions beyond the initial 4 months of participation; greater flexibility in delivery was required for this intervention with adult-child carers, compared with a similar intervention trialled with spousal carers. Mechanisms of impact were improved carers' coping with emotional problems, and support groups were helpful in facilitating participants' management of functional issues.

Birkenhager-Gillesse et al²¹ evaluated a residential intervention for carers. They explored implementation factors through fidelity of delivery, finding that the residential nature may have stimulated workshop attendance and completion. An essential mechanism of impact was modelling—learning from each other's behaviour. This also contributed to group feeling and promoted social support. Boots et al²² evaluated a personalised coaching intervention—using face-to-face coaching alongside tailored web-based modules. Mechanisms of impact were found to be personalised content, a blended approach, and a familiar personal coach; while lack of carer computer literacy, carer burden and high staff workload were contextual barriers. The authors recommended adapting content to specific subgroups, for example younger carers. Clare et al³³ evaluated a goal-oriented cognitive rehabilitation intervention using face-to-face therapy sessions and found a key mechanism of impact was the dyad's relationship with the therapist, as well as the dyads expressed need for social contact and support. A key implementation factor was greater individual tailoring and flexibility of content, thought to lead to better outcomes.

Three process evaluations of interventions primarily seeking to change behaviour of PLWD, similarly found common themes of mechanisms of impact: in the need for flexibility in approach and engagement of carers. Sprange et al¹⁴ noted that a 'one size fits all' intervention design approach cannot accommodate the complexity of dementia. In Chester et al's²³ evaluation of an intervention providing personalised care packages, family dynamics and carer engagement with the intervention had mediating influences, as did ability of the facilitator to take a sensitive, individualised approach. Contextual factors were difficulty in maintaining professional boundaries due to co-morbidities, which was addressed through signposting participants to other resources, and timeliness of the intervention after diagnosis.

Matching interventions to stage of dementia was also pertinent in the evaluation by Voight-Radloff et al¹⁸ of a community occupational therapy programme, which concluded that participants did not use the intervention as they had insufficient need for it. Finally, Walton et al¹² explored how to improve fidelity of delivery and engagement to a manualised self-management feasibility intervention aiming to increase independence of the PLWD. Factors influencing engagement were found to be personal attributes, capability, and opportunity to engage with the intervention components. The process evaluation went on to apply the findings to create strategies to improve future fidelity and engagement to increase the effectiveness of the intervention.

Where staff were involved in delivery, it was critical interventions were adequately staffed and perceived the benefits of the intervention. The final two evaluations^{19,28} of face-to-face

psycho-education interventions targeted professionals. Key mechanisms of impact were the extent to which proposed interventions were considered necessary by professionals,²⁸ the amount of training professionals attended and the extent to which they followed protocols.¹⁹

3.7.2.2 Online psycho-education interventions^{20,24,27,29,31}

Beentjes et al²⁰ and Kerkhof et al²⁹ evaluated a pilot trial of a digital application aiming to improve self-management and participation in daily social activities. Beentjes et al²⁰ considered that the training for participants was insufficient, and PLWD required help downloading applications. Motivation to learn how to use a tablet was a key mechanism of impact. Kerkhof et al²⁹ evaluated the feasibility of implementation strategies. Training proved helpful for carer and PLWD, although one face-to-face training session was not sufficient, and PLWD had difficulties with swiping and tapping on touchscreens.

Huis in het Veld et al²⁷ showed variation in the extent carer's made use of online intervention components, and not all components were delivered/ completed. Contextual findings were that participants already had information on dementia and therefore may not have used the components as intended. Dam et al²⁴ carried out a process evaluation on an intervention delivering a social support platform to carers of PLWD. Findings relating to implementation were the structure, layout, and content were clear and user-friendly, although adherence was not optimal. Mechanisms of impact were active engagement from other members.

Finally, Van Knippenberg et al³¹ evaluated an intervention using an experience-sampling method for carers. A key mechanism of impact was the feedback received, which was found to be supportive and increased participants awareness of their feelings and behaviour. Also, the personal coach was important in feedback and encouragement. The authors found a significant variability in how participants applied the feedback into their daily lives.

3.7.2.3 Integrated findings on how MRC guidance was applied

We applied a lens of the MRC guidance to understand what components across implementation, mechanisms of impact, and contextual factors the evaluations evaluated, and what components influenced outcomes for this population:

Contextual factors: Only 8 out of 24^{10,12,18,20,23,25,32,33} of evaluations explicitly considered contextual factors in their design. Contextual factors however were key throughout 20 of the findings of the included evaluations. These strongly related to the carer, including their motivations^{12,25,33} attitudes^{11,17,23,26} and knowledge of dementia^{13,16,33}, and time,^{12,17,31} effort,^{11,24,30,31,32} and/or ability^{15,16,30,32} to carry out the intervention components/ activities. If carers were too burdened to support interventions (especially when they were online), they were often less effective. The participant's need for the intervention and stage of dementia were key influencing factors for success across the interventions. Some interventions mentioned their success was due to timeliness,^{23,24,33} whereas others that a barrier was participants' lack of need.^{18,22,25} Adherence to exercise interventions was better when PLWD were more motivated and aware of potential benefits; for these and other interventions requiring active engagement in computer-guided tasks or dyadic interventions, implementation was less successful with greater levels of impairment. By contrast a community occupational therapy intervention focused on functional impairment reported low adherence, possibly because the participants were not sufficiently functionally impaired to require it,¹³ and a group-based exercise class reported transportation issues to the class as negatively impacting the adherence.³²

Factors of implementation: Interventions targeting family carers needed to be flexible and supportive. Adaptation of content for individual dyads,^{12,22,25,33} ensuring the intervention is

deliverable,^{14,18,19,23,25,31} flexibility in when dyads were able to carry out the activities,¹⁰ and easy to use²⁴ were key factors for change associated with implementation.

Mechanisms of impact: A very commonly identified mechanism of impact (15 out of 24 of evaluations) was the importance of providing support for the carer of the PLWD, whether from facilitators or peers. Interventions that had an element of support for carers, either online,^{24,27} face-to-face,^{15,30,31} attending support groups with facilitators and/or peers,^{10,11,13,14} or by individual or group counselling or therapy sessions,^{10,13,14,27,33} or included social interactions,³² benefitted dyads. Another key mechanism of impact was participants' engagement with the intervention; high engagement and enjoyment by dyads facilitated change,^{14-17,29-31,33} and low engagement and low enjoyment was a barrier.^{24,14,15} Routine was also found to be an influencing factor, whether the routine of delivery²⁵, or the dyads' ability to build the intervention activities into a routine.^{15,26,31}

Positive feedback loops where the intervention was found to be helpful, for example in improving mood^{14-17,29-32} or establishing routines,^{15,25,26,31} were key mechanisms of impact. Interventions that were not too complicated^{14,18,19,23,25,31} and provided quality training,^{12,14,20,29} were associated with greater adherence. For computer-based interventions, computer literacy was key.^{16,20,22,29,31}

4. DISCUSSION

This systematic review examined 24 studies evaluating 22 psychosocial interventions for enhancing wellbeing and life quality of community-dwelling people with dementia and their family carers. We summarise below our findings in relation to the two aims of this review.

4.1 Aim 1: To understand how process evaluations and evaluations are being applied in this field.

Only a quarter of the included studies used an intervention theory to inform the design of the process evaluation. The MRC Guidance⁵ mentions the importance of understanding and drawing upon the theories underpinning the intervention, to test and refine them. The underpinning programme theory is also a core element to consider in the new MRC framework,³⁸ which describes how theory-based evaluations should prioritise theory-building to understand how outcomes or system behaviour are generated through interventions. This review echoes the findings by McIntyre et al⁸ regarding the limited implementation of intervention theory into process evaluation design. Future process evaluations should prioritise using a theory-based approach to gain a deeper understanding of how these interventions influence change for this population, so that results are more generalisable and useful in future intervention design.

Secondly, only a quarter of included studies explicitly considered contexts in the design of their interventions, though most discussed how contexts influenced findings. A more theoretical and strategic approach to considering contexts would enhance the evidence base regarding what psychosocial interventions work for whom, in what circumstances. This is particularly pertinent with the complexity inherent in dementia care. These findings reflect why the new MRC framework³⁸ emphasises that complex intervention effects might be highly dependent on context, whereby an intervention could be effective in some settings but not others.

None of the process evaluation frameworks used in included studies (Figure 3) are prescriptive. Overall recommendations across all frameworks (figure 3) are to use mixed-methods and integrate data sets to better understand the factors operating across all

intervention components. We recommend future process evaluations follow this design to enable greater depth of understanding.

4.2 Aim 2: To generalise the key findings across the included evaluations of psychosocial interventions to highlight core influencing factors of change for this population.

Key influencing mechanisms of impact were the importance of support for the family carer of the PLWD, whether through the facilitator or through peers, participant engagement with the intervention, and enjoyment of the activities by both the PLWD and the carer. Quality of content and flexibility of delivery of intervention components were core influencing implementation factors.

Key contextual findings were the participants' need for the intervention, as well as timeliness of delivery in line with progression of dementia. Findings regarding the importance of flexibility, support, enjoyment, need, timeliness, perceived helpfulness of interventions, and integration in routines echo previous studies. Caron et al³⁹ for example, described how the degree of informal or formal support for family influences how long PLWD can live at home. Marx et al⁴⁰ have previously highlighted the importance of flexibility and tailoring of interventions. Johnston and Narayanasamy⁴¹ describe the importance in meaningful activities for PLWD; and Kovach et al⁴² and Scholzel-Dorenbos et al⁴³ how interventions should address unmet needs in dementia. Finally, Lord et al⁴⁴ highlighted that carer self-efficacy, practical ability, values, traditions, and resources influence their decisions affecting the PLWD they care for. Thus, this review concurs with previous findings, and highlights the importance of incorporating these as core factors influencing change when developing psychosocial interventions and evaluating them in process evaluations.

4.3 Strengths and limitations

We consider our approach of including all studies that evaluated how an intervention being evaluated in an RCT was working (irrespective of whether they were formally identified as process evaluations) as a strength, ensuring an inclusive approach to the review of relevant evidence. We acknowledge, however, that the application of process evaluation criteria to the analysis of studies not explicitly described as process evaluations might be considered a limitation. While the MMAT tool was sufficiently flexible to encompass most types of included study, it did not have the flexibility to cover process evaluation methodology which collects, analyses and reports qualitative and quantitative data as separate datasets, without intention to utilise mixed-method design; these were rated lower for not using these methods, though it was not their planned intention

5. CONCLUSION

We have summarised the literature regarding how process evaluations are being applied in this field. While a minority have used a theory-based approach and applied a process evaluation framework such as the MRC Guidance⁵ to ensure rigour and consistency across process evaluations—and, as recommended by most frameworks, applied a mixed-methods design—most have not. These findings echo and build on previous literature, as dementia interventions are seeking to influence a complex environment, we strongly recommend that future process evaluations follow these recommendations. Further, we suggest they seek to examine the breadth of contextual factors likely to influence how interventions will work in practice, across diverse situations and populations.

We also sought to generalise the key findings across the included evaluations of psychosocial interventions to highlight core influencing factors of change for this population.

We identified core factors in successful interventions as: actively including and supporting family carers, developing enjoyable and flexible interventions, that are targeted appropriately to the stage of dementia, or sufficiently flexible that they can be tailored to different levels of dementia.

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APPENDIX A

Implementation: what is implemented, and how?	Mechanisms of impact: how does the delivered intervention produce change?	Context: how does context affect implementation and outcomes?	Causal Assumptions
<p>An intervention may have limited effects either because of weaknesses in its design or because it is not properly implemented. On the other hand, positive outcomes can sometimes be achieved even when an intervention was not delivered fully as intended. Hence, to begin to enable conclusions about what works, process evaluation will usually aim to capture fidelity (whether the intervention was delivered as intended) and dose (the quantity of intervention implemented). Complex interventions usually undergo some tailoring when implemented in different contexts. Capturing what is delivered in practice, with close reference to the theory of the intervention, can enable evaluators to distinguish between adaptations to make the intervention fit different contexts and changes that undermine intervention fidelity.</p> <p>In addition to what was delivered, process evaluation can usefully investigate how the intervention was delivered. This can provide policy makers and practitioners with vital information about how the intervention might be replicated, as well as generalisable knowledge on how to implement complex interventions. Issues considered may include training and support, communication and management structures, and how these structures interact with implementers' attitudes and circumstances to shape the intervention.</p> <p>Process evaluations also commonly investigate the "reach" of interventions (whether the intended audience comes into contact with the intervention, and how). There is no consensus on how best to divide the study of implementation into key subcomponents (such as fidelity, dose, and reach), and it is currently not possible to adjudicate between the various frameworks that attempt to do this.</p>	<p>Exploring the mechanisms through which interventions bring about change is crucial to understanding both how the effects of the specific intervention occurred and how these effects might be replicated by similar future interventions. Process evaluations may test hypothesised causal pathways using quantitative data as well as using qualitative methods to better understand complex pathways or to identify unexpected mechanisms</p>	<p>Context includes anything external to the intervention that may act as a barrier or facilitator to its implementation, or its effects. As described, implementation will often vary from one context to another. However, an intervention may have different effects in different contexts even if its implementation does not vary. Complex interventions work by introducing mechanisms that are sufficiently suited to their context to produce change, while causes of problems targeted by interventions may differ from one context to another. Understanding context is therefore critical in interpreting the findings of a specific evaluation and generalising beyond it. Even where an intervention itself is relatively simple, its interaction with its context may still be highly complex.</p>	<p>Causal assumptions may be drawn from social science theory, although complex interventions will often also be informed by other factors such as past experience or common sense. An intervention as simple as a health information leaflet, for example, may reflect an assumption that increased knowledge of health consequences will trigger behavioural change. Explicitly stating causal assumptions about how the intervention will work can allow external scrutiny of its plausibility and help evaluators decide which aspects of the intervention or its context to prioritise for investigation.</p>

Appendix B

Overview of the interventions, intervention theory, participants, primary outcomes and if these were achieved, that were evaluated through the included studies.

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Barrado-Martin (2020)/ Nyman (2019)	Other: Assessing adherence	The TACIT trial: to explore the effects of Tai Chi in improving the postural balance of PLWD/ family cares, which has been related to the prevention of falls over 20 weeks.	Self-efficacy theory (Bandura, 1977), and Self-determination theory (Ingledwet et al, 1998) could help explain sustained Tai Chi practice at home	n=43 intervention, n=42 control	PLWD mean timed up and go score	Not for primary outcome, sig effect for QoL
Beentjes(2020)/ Kerkhof (2020)	Process evaluation alongside RCT	Feasibility pilot RCT 'FindMyApps': Personalised interactive online training application for dyads (PLWD/ informal caregivers) (Kerkhof et al., 2017, 2020, 2019) to find suitable apps for self-management and meaningful activities over 3 months.	Using touchscreen technology may improve well-being of PLWD (Tyack & Camic, 2017). Playing casual games or touchscreen-based art on a tablet may improve PLWD well-being (Tyack, Camic, Heron, & Hulbert, 2017).	n=10 intervention group, n=10 control group	Self-management abilities and participation in daily and social activities.	Yes
Birkenhager-Gillesse(2020)/ same	Process evaluation alongside RCT	Psycho-educational (psychological, educational, and social elements) residential 5-day dyadic intervention 'More at home with dementia' for PLWD and their caregivers	Based on the "Going To Stay at Home" intervention developed in Australia (Gresham et al, 2014)	n=71 intervention, n=71 control	Carer-related quality of life at 3 months and 6 months follow up	No

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Boots (2017)/ same	Process evaluation alongside RCT	Eight-week blended self-care management program 'Partner in Balance' including face-to-face personal coach and evaluation sessions and online thematic modules	Based on The Stress and Coping paradigm (Lazarus & Folkman, 1984), and the Social Learning theory (Bandura, 1997)	n=41 intervention, n=40 waiting-list control	Caregiver self-efficacy and depressive symptoms (*used GAS)	Significant effects were found for self-efficacy care management, and self-efficacy service use. No significant effects were found for depression.
Chester(2021)/ Clarkson (2021)	Process evaluation alongside RCT	Personalised intervention (DESCENT) for PLWD/ family carers using memory aids, training, and support at home to improve the cognitive abilities, function and well-being: 2 face-to-face (core) and 2 telephone(optional) sessions over 4 weeks	An individual's functional decline can be influenced by the home environment and modifications may help maximise their performance of daily activities or tasks. It also had elements of needs and goals-based care. Both models share the underlying aim of supporting people with dementia to live with dementia at home for longer (Lord et al.,2019).	n=234 intervention group, n= 234 control group	Activities of Daily Living	No

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Clare(2019) / same	Process evaluation within RCT	Goal-oriented cognitive rehabilitation for early-stage Alzheimer's and related dementias: the GREAT RCT. 10 week personalised intervention to help people with early-stage dementia to manage everyday activities through cognitive rehabilitation.	Theoretical model of Cognitive rehabilitation (CR) is an individualised, goal-oriented, problem-solving approach aimed at managing or reducing functional disability and maximising engagement and social participation.	n=239 intervention group, n=236 Control	Participant goal attainment rating (3months)	Yes
Dam (2019)/ same	Process evaluation alongside RCT	16-week online social support platform, 'Inlife' to enhance social support, positive interactions and information sharing in informal support networks for caregivers of PLWD.	E-health interventions have shown beneficial results for caregiver self-efficacy, feelings of competence and depression (Boots et al., 2014). Social media interventions could have the potential to stimulate positive interaction and capacities of PLWD and their informal caregivers.	n=48 intervention, n=48 waiting list control group	Caregiver's subjective feelings of competence and perceived social support.	Yes
Di Lorito (2021)/ Bajwa (2019)	Other: Qualitative sub-study	(PrAISED) tailored programme of physical, dual-task exercises, and functional activities of daily living delivered in participants' homes by a multidisciplinary team including physiotherapists (PTs), occupational therapists (OTs), and rehabilitation support workers (RSWs).	Tele-rehabilitation	unknown	Disability in activities of daily living	unknown

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Donkers (2018)/ Additional file within Donkers (2018)	Process evaluation alongside RCT	Tailored multidisciplinary (community occupational therapy and physiotherapy) social fitness (SF) intervention over 6 months to enable social participation for PLWD and their primary caregivers.	Followed the Community Occupational Therapy in Dementia (COTiD) programme to combine active treatment methods (exercises and training of bodily functions, and the effective use of skills and strategies) to improve participation in social activities of the client and caregiver.	n=8 intervention group, n=9 control group	Self-perceived performance and satisfaction on social participation goals.	No (Due to limited inclusion)
Gaugler (2018)/ Gaugler (2013, 2015, 2016)	Process evaluation alongside RCT	Multicomponent (individual and family counselling, support groups, and ad hoc counselling) intervention (NYUCI-AC) for adult child caregivers of PLWD: 6 sessions over 4 months	Conceptually grounded in the stress process model developed by Pearlin and associates emerged in 1990 (Pearlin, Mullan, Semple, & Skaff, 1990), and clinically driven by elements of family systems theory.	n=54 intervention, n=53 control	To examine if the substantial benefits of NYUCI extended to adult child caregivers.	Yes
Goldberg (2019)/ same	Other: RCT feasibility trial	Feasibility trial of PrAISED: tailored exercise-based programme delivered to PLWD/ Carers by a multidisciplinary team including physiotherapists (PTs), occupational therapists (OTs), and rehabilitation support workers (RSWs) over 12 months	Multi-disciplinary rehabilitation intervention using physiotherapy and occupational therapy to support PLWD/ Family carers	PLWD/family carer (n=60 PLWD/ n=54 carers) recruited directly to feasibility trial.	Activities of daily living and cognition	Yes

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Hancox (2019)/ Goldberg (2019)	Other: adherence assessment	Feasibility trial of PrAISED: tailored exercise-based programme delivered to PLWD/ Carers by a multidisciplinary team including physiotherapists (PTs), occupational therapists (OTs), and rehabilitation support workers (RSWs) over 12 months	Multi-disciplinary rehabilitation intervention using physiotherapy and occupational therapy to support PLWD/ Family carers	PLWD/family carer (n=60 PLWD/ n=54 carers) recruited directly to feasibility trial.	Activities of daily living and cognition,	Yes
Huis in het Veld (2021)/ Huis in het Veld (2020)	Process evaluation alongside RCT	12-week online self-management support intervention (personal email contacts and e-bulletins) addressing behavioural changes in dementia for family caregivers of PLWD	Using online 'self-management' (Barlow et al, 2002) to support positive effects on the self-efficacy and other psychological or psychosocial outcomes for family caregivers.	n=27 (major) intervention, n=27 (medium) intervention, n= 27 (minor) intervention	Family caregiver self-efficacy	No
Jansen (2011)/ same	Process evaluation within RCT	Case management intervention for PLWD/ informal caregivers: 2 visits followed by telephone calls every 3 months over 1 year.	Timely recognition and diagnosis of dementia may be a pre-condition for improving care for both older adults with dementia and their caregivers. Case management has also been associated with reductions in burden and depression (Newcomer et al, 1999).	n=54 intervention, n=45 control	Caregiver's sense of competence	No

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Johannessen (2011)/ Bruvik (2014)	Evaluation: Qualitative sub-study	The 'PSI' Program is a multicomponent (education, counselling, and group meetings) RCT program, lasting for 18 months for PLWD/ family carers.	Problem-solving method and use of educational program with counselling and group meetings.	n=115 carers	Unclear	No
Kerkhof (2020)/ same	Evaluation: RCT feasibility trial	FindMyApps: Personalised interactive online training application for PLWD and their informal caregivers (Kerkhof et al., 2017, 2020, 2019) to find suitable apps for self-management and meaningful activities over 3 months.	The errorless learning (EL) method (Clare et al, 2008; de Werd et al, 2013).	n=10 intervention, n=10 control	self-management abilities and participation in daily social activities.	No statistical sig effects.
Lavoie (2005)/ Hebert (2003)	Process evaluation alongside RCT	Multi-component (cognitive appraisal and coping strategies) intervention for family carers of PLWD: 15 two-hour weekly sessions over	Lazarus and Folkman (1984) transactional theory of stress and coping consisting of two components: cognitive appraisal and coping strategies.	n=79 intervention, n=79 control	Frequency of behavioural and memory problems, and informal caregivers' reactions.	Yes

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Leung (2017)/ Orgeta (2015)	Other: Qualitative exploration	The iCST intervention consisted of one-to-one structured cognitive stimulation sessions for PLWD delivered by carers at home over 26 weeks	A theoretical framework of carer involvement in cognition-based interventions (CBIs) for PLWD/ Family carer. Consists of the binding ties theory (Townsend and Franks, 1995), the enrichment process theory (Cartwright et al., 1994) and the scaffolding process theory (Cavanaugh et al., 1989)	n=180 intervention, n=176 control	Cognition and self-reported QoL	No
Mehling(2020)/ same	Process evaluation within RCT	"Paired PLIE (Preventing Loss of Independence through Exercise)' 12-week intervention is a systematically developed integrative group movement program developed for adult day centres targeting abilities and neural mechanisms including; building procedural memory, improving focus and attention and increasing well-being.	The overall structure of PLIE was developed by integrating 'best practices' from a wide range of movement modalities including physical therapy, occupational therapy, recreation therapy, dance movement therapy, yoga, tai chi, Feldenkrais, and Rosen Movement	n=14 intervention group, n=15 delayed start group	Daily activities/ physical function, cognitive function, and quality of life for PLWD. Caregiver distress for carers	For PLWD: Yes for quality of life measure, No for daily activities/physical function or cognitive function. For carers: No

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Prick (2014)/ Prick (2015)	Process evaluation alongside RCT	Multicomponent (exercise and support) dyadic intervention for PLWD/ family carers: 8 home visits over 3 months	Cognitive reframing (based on the ABC theory)	n=57 intervention, n=54 control	To reduce depressive symptoms of PLWD and their caregivers at 6 months and 12 months follow up	No
Spijker (2013)/ Same	Evaluation: Evaluating adherence	Systematic Care Program for Dementia SCPD: training professionals in the systematic assessment and interpretation of caregiver problems and in strategies to deal with deficiencies	Using tailored caregiver support programs to support caregivers (Gitlin et al, 2010).	n=38 professionals, n=155 dyads intervention group, n=28 professionals, 140 dyads in control	adherence to the protocol	No
Sprange (2020)/ Mountain (2017)	Evaluation: embedded qualitative study	Feasibility RCT 'Journeying through Dementia': a multi-component psychosocial community-based intervention involves both group and individual sessions for PLWD/family carers over 12-week program.	The intervention is underpinned by social cognitive theory (Bandura, 1982) with a focus on behaviour change through increased self- efficacy (Bandura, 1982) and effective problem solving (Law et al, 1996)	n=145 intervention, n=143 control	Mental well-being	No

Study/ trial paper	Study type	Intervention evaluated	Theoretical framework/ model used	Trial participants	Primary outcome for main trial	Primary outcome in main trial achieved (Y/N)?
Van Knippenberg (2018)/ same	Process evaluation alongside RCT	Six-week experience sampling method (ESM) intervention 'Partner in Sight' for spousal caregivers of people with dementia.	Based on the 'broaden-and-build theory' (Fredrickson, 1998) using retrospective and in-the-moment daily life assessments (Myin-Germeys et al, 2009).	n= 26 intervention, n=24 pseudo-intervention, n=26 control	To examine the relationship between caregivers' sense of competence and experienced positive affect in daily life after 2 months	No
Voigt-Radloff (2011)/ same	Process evaluation alongside RCT	Community based occupational therapy intervention: 10, 1-hour sessions for 5 weeks for PLWD/ primary care givers verses control group of 1-hour semi-structured consultation assessed over 26 weeks.	Dutch evidence-based Community Occupational Therapy Intervention Dementia Programme (COTiD)	n=71 intervention, n=70 control	Change in daily functioning	No
Walton (2020)/ Csipke (2021)	Process evaluation within RCT	manualised tailored dyadic intervention 'PRIDE' for PLWD/ caregiver (Feasibility RCT) based on principles of self-management: 3 sessions over 2 months	Behaviour Change Wheel (Michie et al, 2011)	n=46 intervention, n=46 control	Feasibility	Yes

