#### **REVIEW ARTICLE**



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. 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:** Twenty four 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

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

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key influencing factors.

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#### **KEYWORDS**

dementia, process evaluation, psychosocial interventions, systematic review, wellbeing

#### Key points

- Interventions for people living with dementia (PLWD) 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.

#### 1 | INTRODUCTION

Dementia is a syndrome involving cognitive decline beyond that expected from biological ageing. An estimated 850,000 UK people live with dementia, with numbers predicted to increase to over 1.2 million by 2030.<sup>2</sup> UK Government policy advocates supporting people living with dementia (PLWD) to retain their independence at home through personalised support and adaptations.<sup>3</sup> 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.<sup>5</sup> Randomised controlled trials (RCT) are regarded as the 'gold standard' for measuring the effectiveness of complex psychosocial interventions.<sup>5</sup> To understand how (in addition to if) an intervention influences change, RCTs can incorporate a process evaluation,<sup>5</sup> to explore how complex interventions generate outcomes, and why they may work within some contexts, for some populations, but not others.<sup>6</sup> 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 2015<sup>5</sup> 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 guidance<sup>5</sup> recommends process evaluations consider (context, mechanism, and implementation factors).

Recent cross-disciplinary systematic reviews<sup>7,8</sup> have found that the term 'process evaluation' is inconsistently used<sup>7</sup>; and that while two thirds of process evaluations cited a theoretical approach, only one quarter were informed by, applied, or tested a theory.<sup>8</sup>

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 guidance<sup>5</sup> process evaluation components for implementation, mechanisms of impact and contextual factors (Figure 1). 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

FIGURE 1 Key functions of Process Evaluation and relations among them. Source: From Moore<sup>5(p. 2)</sup>

education, awareness, support, environmental adaptations, behavioural change and/or management. Due to the inconsistencies around the use of the term 'process evaluation',<sup>7</sup> 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.<sup>9</sup>

#### 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 guidance<sup>5</sup> description of implementation, mechanisms of impact, and contextual factors (Figure 1 and Appendix A).

## 2.5 | Assessing study quality

We used the MMAT Version 2018 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 RCT. 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.

#### 3.2 | Study quality

Out of the 24 included studies, eight evaluations <sup>10–17</sup> answered 'yes' to all MMAT sections, indicating a high level of quality. Two evaluations <sup>18,19</sup> 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. <sup>20–33</sup> 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 <sup>20–22,24,26,28,32,33</sup> 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 <sup>20,22,24,26,32,33</sup> answered yes to all sections relating to their qualitative and quantitative components. Two studies <sup>21,28</sup> answered 'no' or 'can't tell' more than once indicating they did not achieve a high-quality rating for their component parts.

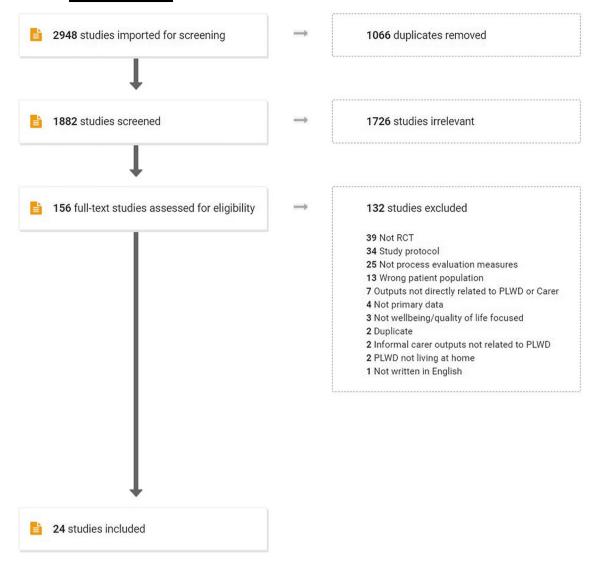


FIGURE 2 PRISMA diagram

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

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

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

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 5 day residential course for carers. <sup>21</sup> They targeted carer outcomes: stress and depressive symptoms, <sup>10</sup> self-efficacy, <sup>22</sup> or quality of life, <sup>21</sup> dyadic relationship quality, <sup>13</sup> or the daily functioning, <sup>18,23,33</sup> independence, <sup>12</sup> behavioural, cognition or

quality of life of the person living with dementia. <sup>11,17</sup> Some psychoeducation interventions were delivered to professionals, with the aim of improving clients' outcomes; including nurse-led case-management for carers, <sup>28</sup> and mental health professionals' training. <sup>19</sup>

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

# 3.4 | Evaluation frameworks

16/24 studies<sup>10–12,18,20–25,27,28,30–33</sup> 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, and two 18,29 the 2008 MRC guidance. The other evaluations used models described by previous authors: three papers 22,24,31 a model from Leontjevas et al., one evaluation a model presented by Reelick et al. And one evaluation were conducted before the MRC guidance was published.

## 3.5 | Research design

Out of the 24 evaluations, eight<sup>10,12,23,25,27,29-31</sup> 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,<sup>10</sup> and explanatory sequential.<sup>12</sup> Six evaluations<sup>20-22,24,26,28</sup> described collecting both qualitative and quantitative data but did not specify integration techniques. Six evaluations<sup>11,13-17</sup> were qualitative studies, all of which were rated as being of higher quality, and two evaluations were quantitative studies.<sup>18,19</sup>

# 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. <sup>10,11,14,15,17</sup> Two of these theories explain how carer stress can be reduced. In their process evaluation of a caregiver intervention, Gaugler et al. <sup>10</sup> 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 al. <sup>11</sup> 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 al. 14 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 al. 15 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 selfperceived ability to perform it, and outcome expectancies. Leung et al.<sup>17</sup> 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.

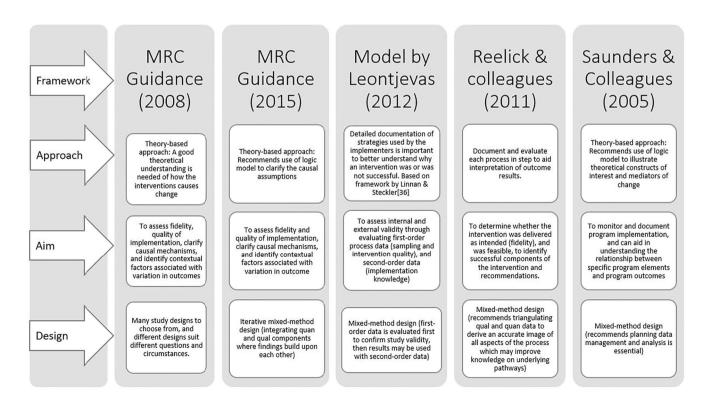


FIGURE 3 An overview of the different frameworks applied. MRC, Medical Research Council

Rather than apply the intervention theory to evaluation design or at the analysis stage, Walton et al.<sup>12</sup> and Hancox et al.<sup>26</sup> deductively applied theory to their findings post analysis, to help interpret their findings. For evaluating their intervention feasibility trial, Walton et al.<sup>12</sup> 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 al.<sup>26</sup> 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

The evaluation aims, components evaluated, and key findings of the included study are shown in Table 1.

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, <sup>10,11,16,23,30</sup> and explored participants' experiences of the intervention. <sup>13,14,17,33</sup>

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<sup>15,16,25,26,30,32</sup>

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 al.<sup>30</sup> commented that efforts to

recruit those with an interest in exercise may have generated a selfselected 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 al.<sup>25</sup> 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 al.<sup>32</sup> found transportation issues to the sessions had a negative impact on class adherence.

Similarly, using solely qualitative methods, Barrado-Martin et al.<sup>15</sup> and Hancox et al.<sup>26</sup> 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 al.<sup>16</sup> 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

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 PLWD more likely to be used. Johannessen et al. <sup>13</sup> found that a dyadic support intervention might work better earlier in the dementia illness. Leung et al. <sup>17</sup> also referenced stage of dementia as an important context to consider in how a carerdelivered individual cognitive stimulation therapy intervention operated. Clare et al. <sup>33</sup> 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 al. <sup>11</sup> 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 al. <sup>10</sup> 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 improved carers' coping with emotional problems, and

(Continues)

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-Martin <sup>15</sup>	Understand what influenced participant adherence	Not specified	Yes	Qual	Dyads	Interviews ( $n = 15$ )	NA	AN A
Beentjes <sup>20</sup>	Evaluating the feasibility of the intervention and research protocol	MRC guidance <sup>5</sup>	o <sub>N</sub>	Quan & qual	Quan & qual Dyads & other stakeholders	Interviews with intervention $(n = 10)$ , control $(n = 10)$ participants & stakeholders	Ordinal questions during interview No	°Z
Birkenhager- Gillesse <sup>21</sup>	Estimate the internal and external validity	MRC guidance <sup>5</sup>	<u>8</u>	Not specified	Dyads	Feedback meeting data and follow- up meetings $(n = 49)$ intervention arm)	Recruitment, reach, and attrition data, training logbook	Unclear
Boots <sup>22</sup>	Determine internal and external validity	Leontjevas <sup>35</sup>	<u>8</u>	Quan & qual	Carer of PLWD & professionals delivering intervention	Focus group & questionnaire ( $n=10$ professionals), participant semistructured interviews ( $n=49$ )	Sampling quality (recruitment, informed consent, allocation, reach), and implementation (components received)	0 Z
Chester <sup>23</sup>	Identify how delivery components are associated with outcomes	MRC guidance <sup>5</sup>	°Z	Mixed- methods	Dyads & interventionists	Practitioner interviews ( $n=5$ )	Analysis of intervention records (delivery and participation factors)	o Z
Clare <sup>33</sup>	To address the process of goal-setting and the process of therapy	Not specified	<sub>Q</sub>	Qual & quan Dyads	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	°Z
Dam <sup>24</sup>	Evaluate the internal and external validity	Leontjevas <sup>35</sup>	o <sub>N</sub>	Qual & quan	Qual & quan Carer of PLWD	Semi-structured interview ( $n = 10$ intervention-arm)	Sampling (recruitment, consent, allocation, reach), intervention (feasibility, fidelity)	o Z
Di Lorito <sup>16</sup>	Explore participants experiences of the intervention	Not specified	°Z	Qual	Dyads	Interviews ( $n = 5$ intervention-arm dyads). Therapists ( $n = 5$ )	٧	₹Z
Donkers <sup>25</sup>	Explore why the trial failed	Saunders et al. <sup>36</sup>	°Z	Mixed- methods	Dyads & interventionists	Questionnaire & focus group/ interview for professionals (n = 16), participant interviews (n = 5)	Analysing telephone interviews, medical records assessed by predefined checklist	O <sub>N</sub>
Gaugler <sup>10</sup>	Identify how delivery components are associated with outcomes	MRC guidance <sup>5</sup>	Yes	Mixed- methods	Carer (adult-child) of PLWD	Open-ended feedback ( $n=54$ )	Process and implementation data, context of care, objective and subjective stressors, depressive symptoms	Yes
Hancox <sup>26</sup>	Explore what influenced participant adherence	Not specified	o Z	Not specified	Dyads	Semi-structured interviews ( $n = 20$ )	Adherence from daily exercise diaries	Yes
Huis in het Veld <sup>27</sup>	Explore what influenced participant adherence	MRC guidance <sup>5</sup>	°Z	Mixed- methods	Carer of PLWD & nurses delivering	Semi-structured interviews ( $n = 12$ carers, & $n = 4$ nurses). Analysis	Actual usage of personal email contact, clicks on video links,	o N
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	Evaluation aim	Framework	Informed by theory	Design	Evaluation participants	Qual data collected	Quan data collected	Data integrated	_W
					the intervention	of email contact content ( $n = 27$ carers and nurses)	clicks on e-bulletin, evaluation survey questions		'ILE'
	Evaluate intervention fidelity and participant satisfaction	Not specified	o Z	Not specified	Carer of PLWD & interventionists	Semi structured interviews with nurses $(n = 3)$	Survey (carer n = 54), hours spent on case management, Caregiver's satisfaction	O <sub>N</sub>	Y_ Geria
	Explore participants experiences of the intervention	Not specified	o Z	Qual	Carer of PLWD	Semi-structured interviews ( $n = 20$ ) NA	٧	<b>Y</b>	rric Psych
	Evaluate the feasibility, implementation strategy and mechanism of impact	MRC guidance <sup>34</sup>	° Z	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 experiences, recruitment	o Z	iatry
	How delivery components are associated with outcomes	Not specified	Yes	Qual	Carer of PLWD & interventionists	Semi-structured interview with carer $(n = 30)$	٧×	ΨZ	
	Explore participants experiences of the intervention	Not specified	Yes	Qual	Dyads	Semi-structured interviews ( $n = 23$ )	<b>∀</b> ک	¥ Z	
	Assess adherence and satisfaction of study components	Not specified	Yes	Quan & qual Dyads	Dyads	Open-ended survey questions $(n = 29)$	Satisfaction survey, participant adherence	o <sub>N</sub>	
	Identify how delivery components are associated with outcomes	Reelick et al. <sup>37</sup>	o Z	Mixed- methods	Dyads	Semi-structured interviews ( $n=11$ ), caregiver activity logs, $\&$ interviewer reflective logs	Recruitment and selection rate, attrition rate, data completeness	Unclear	
	Explore what influenced participant adherence	Not specified	0 Z	Quan	Dyads & interventionists	₹ 2	Training and screening data $(n = 48)$ , carers' depression, sense of competence, distress, PLWD behaviour	₫ Z	
	Explore participants and facilitators experiences of the intervention	MRC guidance <sup>5</sup>	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 $n = 6$ )	VΑ	<b>∀</b> Z	
ا Knippenberg <sup>31</sup>	Determine internal and external validity	Leontjevas <sup>35</sup>	o Z	Mixed- methods	Carer of PLWD & interventionists	Semi-structured interviews ( $n = 20$ intervention-arm)	Sampling (recruitment, randomisation, reach), intervention fidelity	o <sub>N</sub>	WYM
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TABLE 1 (Continued)	ntinued)							
Study	Evaluation aim	Informed Framework by theory Design	Informed by theory	Design	Evaluation participants	Qual data collected	Quan data collected	Data integrated
Voigt-Radloff <sup>18</sup>	Explore why the trial failed	MRC guidance <sup>34</sup>	o Z	Quan	Dyads & interventionists	<b>∀</b> Z	Patient data, therapist expertise, intensity of treatment, study design	A N
Walton <sup>12</sup>	Explore fidelity and participant engagement	MRC guidance <sup>5</sup>	°Z	Mixed- methods	ed- Dyads & methods interventionists	Semi-structured interviews (professionals $n = 8$ , PLWD $n = 7$ , and carers $n = 7$ )	Fidelity and engagement	Yes

support groups were helpful in facilitating participants' management of functional issues.

Birkenhager-Gillesse et al.<sup>21</sup> 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 al.<sup>22</sup> evaluated a personalised coaching intervention—using faceto-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 al. 33 evaluated a goaloriented 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 al.<sup>14</sup> noted that a 'one size fits all' intervention design approach cannot accommodate the complexity of dementia. In Chester et al.'s<sup>23</sup> 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 al. 18 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 al. 12 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, <sup>28</sup> the amount of training professionals attended, and the extent to which they followed protocols. 19

Online psycho-education interventions<sup>20,24,27,29,31</sup>

Beentjes et al.<sup>20</sup> and Kerkhof et al.<sup>29</sup> evaluated a pilot trial of a digital application aiming to improve self-management and participation in daily social activities. Beentjes et al.<sup>20</sup> 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 al.<sup>29</sup> 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 al.<sup>27</sup> 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 al.<sup>24</sup> 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 al.<sup>31</sup> 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.

Integrated findings on how MRC guidance was applied

We applied a lens of the MRC guidance<sup>5</sup> 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<sup>10,12,18,20,23,25,32,33</sup> 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, <sup>13,16,33</sup> and time, <sup>12,17,31</sup> effort, <sup>11,24,30-32</sup> 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, <sup>13</sup> and a group-based exercise class reported transportation issues to the class as negatively impacting the adherence.<sup>32</sup>

Factors of implementation: Interventions targeting family carers needed to be flexible and supportive. Adaptation of content for individual dyads, <sup>12,22,25,33</sup> ensuring the intervention is deliverable, <sup>14,18,19,23,25,31</sup> flexibility in when dyads were able to carry out the activities, <sup>10</sup> and easy to use<sup>24</sup> were key factors for change associated with implementation.

Mechanisms of impact: A very commonly identified mechanism of impact in 15 out of 24 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, <sup>24,27</sup> face-to-face, <sup>15,30,31</sup> attending support groups with facilitators and/or peers, <sup>10,11,13,14</sup> or by individual or group counselling or therapy sessions, <sup>10,13,14,27,33</sup> or included social interactions, <sup>32</sup> benefitted dyads. Another key mechanism of impact was participants' engagement with the intervention; high engagement and enjoyment by dyads facilitated change, <sup>14–17,29–31,33</sup> and low engagement and low enjoyment was a barrier. <sup>14,15,24</sup> Routine was also found to be an influencing factor, whether the routine of delivery, <sup>25</sup> or the dyads' ability to build the intervention activities into a routine. <sup>15,26,31</sup>

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 Guidance<sup>5</sup> 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,<sup>38</sup> 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 McIntrye et al.<sup>8</sup> 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 framework<sup>38</sup> 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 al.<sup>39</sup> for example, described how the degree of informal or formal support for family influences how long PLWD can live at home. Marx et al.<sup>40</sup> have previously highlighted the importance of flexibility and tailoring of interventions. Johnston and Narayanasamy<sup>41</sup> describe the importance in meaningful activities for PLWD; and Kovach et al.<sup>42</sup> and Scholzel-Dorenbos et al.<sup>43</sup> how interventions should address unmet needs in dementia. Finally, Lord et al.<sup>44</sup> highlighted that carer self-efficacy, practical ability, values, traditions, and resources influence their decisions affecting the PLWD they care for. Thus, this review concords 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 Guidance<sup>5</sup> 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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# **CONFLICT OF INTEREST**

The authors declared that they have no conflicts of interest to this work.

#### DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials.

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#### SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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