



Evidence Appraisal Report

Strategies for Relatives (START) intervention to improve the mental health of carers of people with dementia

Appraisal summary

The purpose of this evidence appraisal report was to identify and summarise evidence that addresses the following question: What is the clinical effectiveness and cost effectiveness of the Strategies for Relatives (START) intervention aimed at improving the mental health of carers of people with dementia?

The vast majority of people with dementia are cared for at home and it is estimated that 700,000 people in the UK act as unpaid informal carers. Dementia is characterised by difficulties with cognition, communication, motor performance, and everyday functioning. The nature and extent of these difficulties can vary according to the stage of progression and dementia sub-type. Due to these difficulties, people with dementia may need support from close relatives or friends.

Caregiving presents serious challenges and can be a highly stressful experience that places strain on relationships and wellbeing. Recent estimates suggest that the prevalence of anxiety and depression is over 30% in carers and the COVID-19 pandemic may have exacerbated this situation. Addressing this issue is of high importance to ensure the health and wellbeing of carers who take on an essential role within society and to prevent the breakdown of care that could lead to need for residential care. Welsh Government has highlighted that effective psychological interventions play an important role in supporting carers but availability is currently limited in Wales.

A series of studies that report on a UK-based trial of the START intervention were identified. START appears effective in reducing symptoms and cases of depression and improving the quality of life of carers compared with usual care. Recent meta-analyses on the effectiveness of similar interventions were also included to provide evidence on whether the findings of the START trial are plausible and reflective of findings with similar interventions. Economic evidence from the START trial suggests that the use of START is cost-effective for carers of people with dementia with an incremental cost effectiveness ratio (ICER) of £12,400 per QALY. When the costs accrued to both carer and recipient of care are included, START may be cost saving.

Health Technology Wales worked with the Alzheimer's Society to facilitate focus group with people with dementia and carers to discuss relevant issues. The Alzheimer's Society also disseminated a questionnaire to their wider patient and care community and relevant literature was reviewed. The focus groups, questionnaires, and literature highlight significant burden placed on the mental health and wellbeing of people who provide care for people with dementia as well as a current paucity of support.

1. Purpose of the evidence appraisal report

This report aims to identify and summarise evidence that addresses the following question: What is the clinical effectiveness and cost effectiveness of the Strategies for Relatives (START) intervention aimed at improving the mental health of carers of people with dementia?

Evidence Appraisal Reports are based on rapid systematic literature searches, with the aim of identifying the best clinical and economic evidence on health technologies. Researchers critically evaluate this evidence. The draft Evidence Appraisal Report is reviewed by experts and by Health Technology Wales (HTW) multidisciplinary advisory groups before publication.

2. Health problem

The vast majority of people with dementia are cared for at home and it is estimated that 700,000 people in the UK act as unpaid informal carers (Lewis et al. 2014). Dementia is characterised by difficulties with cognition, behaviour motor performance, and everyday functioning and the nature and extent of these difficulties can vary according to stage of progression and dementia sub-type (Arvanitakis et al. 2019). Due to these difficulties, people with dementia may need support from close relatives or friends who take on the role of unpaid informal carer. Caring responsibilities can be varied and relate to the needs of person with dementia but typically involve providing practical (e.g. household tasks, managing medication), personal (e.g. dressing, bathing), and emotional support (NHS England 2021). As dementia becomes more severe, formal care in the home or placement in a residential setting may be needed, but unpaid informal carers are central to ensuring that people with dementia are supported to live independently and in their own home for as long as possible. 'A Healthier Wales' recognises the vital role that carers provide and acknowledges that, without them, there would not be a functioning social care system (Welsh Government 2018).

For carers, some aspects of caregiving are associated with positive experiences and consistent care from a person known to the recipient of care can be the optimal arrangement (Lindeza et al. 2020). However, caring presents serious challenges and can be a highly stressful experience that places strains on relationships and wellbeing. (Lindeza et al. 2020, Alzheimer's Research UK 2015). Caregivers have high rates of mental health problems compared to the general population and the demands of caring appear to play a driving role in this. Recent meta-analysis report pooled prevalence estimates of over 30% for both anxiety and depression in carers of people with dementia, with women at higher risk for depression (Collins & Kishita 2020, Kaddour & Kishita 2020). Similarly, a recent study on the impact of the COVID-19 pandemic found that presence of anxiety and depression symptoms were substantially higher in carers than in the general population (Mak et al. 2021). Addressing this issue is of high importance to ensure the health and wellbeing of carers who take on an essential role within society and to prevent care breakdown that may lead to earlier than needed placement in residential care (Gallagher et al. 2011).

3. Health technology

The Strategies for Relatives (START) programme is an eight session manualised intervention that supports the development of coping strategies using both psychoeducational and cognitive behavioural approaches (University College London 2021). It was adapted from the American "Coping with Caregiving Programme" by researchers at University College London. The content and style was changed to be appropriate and feasible for delivery in the UK. The eight sessions are structured around education about dementia and caring, discussing behaviours and situations the carer finds difficult, developing adaptive coping strategies, planning pleasant activities, and maintain skills over time. The sessions are delivered to individuals in a setting that they prefer, usually the home, and therapists support carers to consider challenges and develop their own solutions, rather

than providing direct answers or professional advice themselves (Livingston et al. 2014b). Through this, the aim is to modify behavioural, cognitive, and affective responses to caregiving and to support the development of coping strategies that reduce stress and improve mental health. START was highlighted by the topic proposer as it has been evaluated in the UK setting and is already under development in some parts of Wales.

National Institute of Health and Care Excellence (NICE) guidance (NG97) on dementia recommends that carers of people with dementia should receive support (NICE 2018). The recommendations outline that support programmes should include psychoeducation and skills components that support people to adapt to living with a person with dementia, and maintain their own physical and mental health. The guidance further recommends that support should be tailored to individual needs and preferences, be specifically designed for those supporting people with dementia, and be at locations that are easily accessible. The NICE quality standard for dementia (QS184) incorporates these recommendations and quality statement 7 outlines the metrics by which delivery of these programmes should be measured (NICE 2019). While the guideline recommends a range of approaches, they noted that the START was a good representation of the topics that should be covered and that it was supported by the best quality economic evidence.

Despite these guidelines, the Welsh Government have recognised that provision of psychological support for carers is inconsistent in Wales and experts note that access varies across local health boards. As a result, extending access to psychological support has been included as a way of meeting the priority to support life alongside caring in their strategy for unpaid carers (Welsh Government 2021).

4. Clinical effectiveness

A series of studies reporting on a randomised controlled trial (RCT) of the START intervention were identified and included in this review (Livingston et al. 2013, Livingston et al. 2014a, Livingston et al. 2020). In addition, a large body of evidence on the effectiveness of similar interventions for carers of people with dementia was identified, including a high number of systematic reviews and meta-analyses. A recent and comprehensive meta-analysis that reported on a range of relevant outcomes was considered relevant and included to provide supporting evidence for the wider approach that supports the START programme (Walter & Pinquart 2020). In addition, a meta-analysis that reported on health-related quality of life (HRQoL), disaggregated from other measures of subjective wellbeing, was included for the same reason (Lee et al. 2020). More detail on the evidence identification and selection process is available in Section 11.

4.1 Evidence on the effectiveness of the Strategies for Relatives (START) intervention

The review identified four articles that published a series of clinical outcomes across differing follow-up periods for an RCT on the effectiveness of the START intervention (Cooper et al. 2016, Livingston et al. 2013, Livingston et al. 2014a, Livingston et al. 2020). Details of this RCT are shown in Table 1 and results are reported in Table 2.

The trial team conducted an RCT to evaluate the effectiveness of the START intervention and recruited carers from three memory services and one neurology clinic across London and the South East of England. Carers were considered eligible if they provided at least weekly support to a person with dementia and identified themselves as the primary care. Participants were randomised to receive either the START intervention or treatment as usual (TAU) for their recruitment centre. They were then followed up to period of six years and both clinical and cost outcomes were assessed.

In total, 472 carers were assessed for eligibility and 260 were randomised with 2:1 ratio to facilitate analysis of clustering by therapist in the intervention arm (intervention n=173; TAU n= 87). Carers

had a mean age of 62.0 years in the intervention group and 56.1 years in the TAU group and their relationship to the recipient of care was mainly partner (total, 42%) or adult child (total, 44%). Most lived with the recipient of care (START, 65.3%; TAU 57.5%) The majority of carers were female (START, 67.1%; TAU 71.3%), were married (START, 64.7%; TAU 71.3%), and in the majority of cases the carer lived with the person with dementia (START, 65.3%; TAU 57.5%). People from minority ethnic groups were well-represented (START, 18.0%; TAU, 19.5%) and education levels ranged from no formal qualifications (START, 26.0%; TAU 20.7%) to further education (START, 44.5%; TAU 41.4%).

The trial also reports on characteristics of people with dementia who were recipients of care. They were older (START, 79.9 years; TAU, 78.0 years) than carers but had broadly similar characteristics with relation to sex, ethnicity, marital status, and education. Recipients of care had a mean Neuropsychiatric Inventory (NPI) score of 24.0 in the intervention and 26.6 in the TAU group, with these scores indicative of mild to moderate neuropsychiatric symptomology. The majority scored either one (START, 53.2%; TAU, 49.4%) or two (intervention, 28.1%; TAU, 34.5%) on the Clinical Dementia Rating (CDR) scale, with these scores being indicative of mild to moderate dementia.

Table 1. Strategies for Relatives (START) compared to treatment as usual: design and characteristics

Reference	Study Design	Intervention and Comparator	Relevant outcomes	Additional notes / Comments on applicability
Livingston et al. (2013)	Randomised controlled trial	Intervention:	<ul style="list-style-type: none"> • HADS total score • HADS subscale scores • Cases of depression and anxiety based on HADS cut-offs • Quality of life for carers and recipients of care • Time to transition from home to care or death • Abusive behaviour from carers towards recipients of care 	<p>The population was generally recruited at a time when recipients of care dementia was relatively mild and were beginning engagement with secondary care. This may mean results are most generalisable to people at this stage of care.</p> <p>Participants were mainly children or partners of the person with dementia. In-laws, nieces and nephews, siblings, and friends were also represented.</p> <p>Most (around 75%) participants completed all eight sessions of START and study investigators rated the fidelity of delivery by psychology graduates as very high.</p> <p>The trial team had initially planned to develop culturally appropriate manuals for different groups but in focus groups found that a single manual incorporating changes recommended by groups from different cultural backgrounds was appropriate. Manuals were translated if needed.</p>
Livingston et al. (2014a)	Multicentre (n=4, England)	START is an eight-session, manualised, individualised therapy programme.		
Livingston et al. (2020)	Enrolment period: November 2009 to June 2011	Sessions cover: psychoeducation about dementia and carer stress; discussion of difficult situations with considered of self-care skills, strategies for changing negative thoughts, effective communication, and positive reframing; future needs of patients and planning of pleasant activities; strategies for maintaining skills over the long-term.		
Cooper et al. (2016)	Follow-up: Six years	The intervention can be delivered by psychology graduates under supervision of a clinical psychologist. Delivery was flexible with most participants seen at home but some seen in NHS settings or their workplace. Evening and out-of-hours sessions were available if required.		
		Comparator:		
		Treatment as usual, including ongoing assessment of dementia, drug treatment and management, cognitive stimulation therapy, and practical support.		

HADS: hospital anxiety and depression scale, START: strategies for relatives.

4.1.1 Mental Health (composite scores)

At eight months, Livingston et al. (2013) reported a significant reduction in mean total score on the hospital anxiety and depression scale (HADS) in START group compared with the TAU group (adjusted mean difference -1.46 ; 95% confidence interval [CI] -2.89 to -0.03). This significant reduction was maintained at 24 month follow-up. An analysis at six years of follow-up found that the average difference across that time period was also significant (Livingston et al. 2014a, Livingston et al. 2020). The differences reported here were adjusted according to baseline score and centre of recruitment and sensitivity analyses using a wider range of variables suggested a larger effect.

4.1.2 Depression

At eight months, Livingston et al. (2013) reported a significant reduction in both mean score on the HADS depression subscale (adjusted mean difference -0.88 ; 95% CI -1.68 to -0.09) and on number of cases meeting the cut-off for depression (odds ratio 0.25; 95% CI 0.08 to 0.81) in the START group compared with the TAU group. These differences were maintained at later follow-ups (Livingston et al. 2014a, Livingston et al. 2020) and other analyses adjusting for a wider range of variables suggested a larger effect. The difference in subscale score is judged as clinically meaningful, according to thresholds set by previous studies of the HADS.

4.1.3 Anxiety

At eight months, Livingston et al. (2013) did not find differences between the START and TAU groups on mean score on the HADS anxiety subscale (-0.62^{\wedge} ; 95% CI -1.43 to 0.19) or the number of cases meeting the cut-off for anxiety (OR 0.35; 95%CI 0.11 to 1.18). At later follow-up, differences for these outcomes were not seen in models adjusted for centre and baseline score. However, there did appear to be reductions on the HADS anxiety subscale score when adjusted for carer and recipient of care characteristics and burden of caring.

4.1.4 Quality of life of carer and recipient of care

Carers quality of life was found to be higher for those receiving START compared to TAU at both eight months (adjusted mean difference 4.55; 95% CI 0.92 to 8.17) and 24 months follow-up (adjusted mean difference 7.16; 95% CI 2.72 to 11.60).

The quality of life of recipients of care was not found to be different across intervention and control groups at any time point. Carer and recipient of care quality of life outcomes were not reported at six year follow up.

4.1.5 Transition to care home or death of recipient of care

There was no difference between either the rate of transition from home to a care home or mortality for the recipient of care between the START and TAU groups across either model-based or Kaplan–Meier analyses.

4.1.6 Abusive behaviour

The presence of abusive behaviour from carer to the recipient of care did not appear to be reduced by START compared with TAU (odds ratio 0.59, 95% CI 0.27 to 1.28). The authors note that they intervened when abusive behaviour was identified and ensured an appropriate plan was put in place and it is possible that this has concealed an effect.

Table 2. Strategies for Relatives (START) compared to treatment as usual: outcomes

Outcome	Study	Follow-up	Number of participants	Baseline value (mean and standard deviation unless stated)	Relative effect
Mental Health (composite scores)					
HADS - Total Score	Livingston et al. (2013)	8 months	229 participants	START: 13.5 (7.3) Control: 14.8 (7.4)	aMD -1.46 [^] (95% CI -2.89 to -0.03) Favours START
	Livingston et al. (2014a)	24 months	209 participants	As above	aMD -1.84 [^] (95% CI -3.50 to -0.17) Favours START
	Livingston et al. (2020)	6 years	222 participants	As above	aMD -1.45 [#] (95% CI -2.80 to -0.10) Favours START
Depression					
HADS - Depression subscale score	Livingston et al. (2013)	8 months	229 participants	START: 5.4 (3.8) Control: 5.5 (3.9)	aMD -0.88 [^] (95% CI -1.68 to -0.09) Favours START
	Livingston et al. (2014a)	24 months	209 participants	As above	aMD -1.14 [^] (95% CI -2.00 to -0.28) Favours START
	Livingston et al. (2020)	6 years	222 participants	As above	aMD -0.93 [#] (95% CI -1.63 to -0.24) Favours START
Cases of depression (score of ≥9 on HADS depression subscale)	Livingston et al. (2013)	8 months	229 participants	START: 21% Control: 20%	OR 0.25 [^] (95% CI 0.08 to 0.81) Favours START
	Livingston et al. (2014a)	24 months	209 participants	As above	OR 0.22 [^] (95% CI 0.05 to 0.96) Favours START
	Livingston et al. (2020)	6 years	222 participants	As above	OR 0.30 [#] (95% CI 0.13 to 0.71) Favours START

Outcome	Study	Follow-up	Number of participants	Baseline value (mean and standard deviation unless stated)	Relative effect
Anxiety					
HADS - Anxiety subscale score	Livingston et al. (2013)	8 months	229 participants	START: 8.1 (4.4) Control: 9.3 (4.3)	aMD -0.62 [^] (95% CI -1.43 to 0.19) Favours neither
	Livingston et al. (2014a)	24 months	209 participants	As above	aMD -0.75 [^] (95% CI -1.75 to 0.25) Favours neither
	Livingston et al. (2020)	6 years	222 participants	As above	aMD -0.58 [#] (95% CI -1.39 to 0.22) Favours neither
Cases of anxiety (score of ≥9 on HADS anxiety subscale)	Livingston et al. (2013)	8 months	229 participants	START: 49% Control: 55%	OR 0.35 [^] (95% CI 0.11 to 1.18) Favours neither
	Livingston et al. (2014a)	24 months	209 participants	As above	OR 0.53 [^] (95% CI 0.24 to 1.16) Favours neither
	Livingston et al. (2020)	6 years	222 participants	As above	OR 0.64 [#] (95% CI 0.31 to 1.32) Favours neither
Quality of life for carers					
Health status questionnaire – mental health domain	Livingston et al. (2013)	8 months	219 participants	START: 58.3 (22.4) Control: 58.2 (21.7)	aMD 4.55 [^] (95% CI 0.92 to 8.17) Favours START
	Livingston et al. (2014a)	24 months	189 participants	As above	aMD 7.16 [^] (95% CI 2.72 to 11.60) Favours START
Quality of life for recipients of care					
Quality of life – Alzheimer's disease	Livingston et al. (2013)	8 months	205 participants	START: 30.2 (6.9) Control: 29.9 (6.9)	aMD 0.80 [^] (95%CI -0.45 to 2.05) Favours neither

Outcome	Study	Follow-up	Number of participants	Baseline value (mean and standard deviation unless stated)	Relative effect
	Livingston et al. (2014a)	24 months	174 participants	-	aMD 0.16 [^] (95%CI -1.30 to 1.63) Favours neither
Transition to care home or death of recipient of care					
Rate of transition from home to care home	Livingston et al. (2020)	6 years	260 participants	NA	IR 0.88* (95% CI 0.58 to 1.35) Favours neither
Rate of mortality	Livingston et al. (2020)	6 years	260 participants	NA	IR 0.81* (95% CI 0.50 to 1.30) Favours neither
Abusive behaviour from carer towards recipient of care					
Presence of abusive behaviour (MCTS score of ≥ 2 on any item)	Cooper et al. (2016)	24 months	213 participants	START: 50% Control: 40%	OR 0.59 (95% CI 0.27 to 1.28) Favours neither
[^] adjusted for baseline score and centre; [#] adjusted for baseline score, centre, and time to give averaged difference over follow-up; *model-based analyses adjusting for baseline HADS-T, centre, carer age and gender, baseline carer recipient symptoms and burden aMD: adjusted mean difference, CI: confidence interval, HADS: hospital anxiety and depression scale, IR: intensity ratio, MCTS: modified conflict tactics scales, NA: not applicable, OR: odds ratio, START: strategies for relatives.					

4.2 Evidence on effectiveness of psychological interventions from secondary evidence

Two meta-analyses on the effectiveness of psychological interventions for carers of people with dementia were included (Lee et al. 2020, Walter & Pincourt 2020). Both reported outcomes separately for cognitive behavioural therapy (CBT) and psychoeducation. Details of the systematic reviews and their findings are reported below and summarised across Table 3 and 4.

Walter & Pincourt (2020) aimed to provide a comprehensive synthesis of studies on the effectiveness of a range of interventions for carers and updated a previous review in this area. Studies were considered eligible if an intervention was compared to a control and authors judged that assignment was implemented or analysed in a way that should not lead to systematic between-group differences at pre-treatment (e.g. by randomised, by propensity score matching). The included outcomes and common measures of outcomes are as follows: burden of caring (Zarit Burden Interview), depression (Centre for Epidemiological Studies Depression Scale), anxiety (Hospital Anxiety and Depression scale), subjective wellbeing (including measures of quality of life, life satisfaction, and other constructs), and symptoms of care recipient. Outcomes were reported according to time from intervention and divided into immediate and follow up time periods.

In order to provide pooled estimates across a range of measures for each outcome, effect sizes were computed for each study and Hedges' *g* statistics were reported. Data on the effectiveness of cognitive behavioural therapy and psychoeducation compared with standard care are reported separately and are included in this review. Hedges' *g* values of 0.15, 0.40, and 0.75 are typically considered small, medium, and large effect sizes. The authors note that categorisation of intervention types can be ambiguous and the distinction between CBT and psychoeducation is often blurred.

Lee et al. (2020) focused on the effectiveness of psychological intervention on health-related quality of life. Randomised controlled trials were considered eligible and measures included the World Health Organization (WHO) Quality of Life, Dementia Quality of Life, Short Form-12 items, and EQ-5D. Effect sizes for each study were computed and corrected for small sample biases and data was pooled using random-effects models. Data on the effectiveness of cognitive behavioural therapy and psychoeducation are reported separately and are included in this review. The authors do not report how follow-ups of differing time periods were considered in the analysis and the authors note only global scores from HRQoL measures were included in analysis. Observed effects may have been different if sub-scales focused on mental health domains of HRQoL were considered.

4.2.1 Burden

For CBT, Walter & Pincourt (2020) reported small to medium effect sizes for reduction in burden of caring at both immediate (effect size -0.37, 95% CI -0.49 to -0.24; $p < 0.001$) and follow up time periods (effect size -0.32, 95% CI -0.58 to -0.05; $p < 0.05$) compared to TAU. For psychoeducation, smaller effect sizes were found for immediate (effect size -0.21, 95% CI -0.28 to -0.13; $p < 0.001$) and follow up time periods (effect size -0.28, 95% CI -0.42 to -0.14; $p < 0.001$) compared to TAU.

4.2.2 Depression

For CBT, Walter & Pincourt (2020) reported small to medium effect sizes for reduction in depression at both immediate (effect size -0.33, 95% CI -0.44 to -0.21; $p < 0.001$) and follow up time periods (effect size -0.31, 95% CI -0.52 to -0.10; $p < 0.01$) compared to TAU. For psychoeducation, similar results were found for immediate (effect size -0.23, 95% CI -0.32 to -0.14; $p < 0.001$) and follow up time periods (effect size -0.26, 95% CI -0.42 to -0.10; $p < 0.01$).

4.2.3 Anxiety

For CBT, Walter & Pincourt (2020) report an effect on anxiety for the immediate time point (effect size -0.37, 95% CI -0.69 to -0.05; $p < 0.05$) compared to TAU but not at later points (effect size -0.34, 95% CI -0.75 to 0.07; non-significant [NS]). For psychoeducation, the reverse is found with no effect seen immediately (effect size -0.24, 95% CI -0.54 to 0.06; NS) but a later effect found (effect size -0.29, 95% CI -0.82 to 0.14; $p < 0.001$). All four of these analyses had limited studies to draw from.

4.2.4 Subjective wellbeing and quality of life

Walter & Pincourt (2020) report no immediate effect for CBT (effect size 0.22, 95% CI -0.01 to 0.44; NS) but find a small effect over the longer term (effect size 0.35, 95% CI 0.03 to 0.66; $p < 0.05$) and an effect for both immediate (effect size 0.27, 95% CI 0.10 to 0.44; $p < 0.01$) and longer term was found for psychoeducation (effect size 0.35, 95% CI 0.08 to 0.62; $p < 0.01$) compared to TAU.

For HRQoL alone, Lee et al. (2020) found large effects for CBT (effect size 0.767, 95% CI 0.142 to 1.391; $p = 0.016$) compared to TAU. For psychoeducation, effects were not significant (effect size 0.163, 95% CI -0.001 to 0.328; $p = 0.052$). However, the confidence interval suggests that a small effect may be present.

4.2.5 Symptoms of care recipient

For CBT, Walter & Pincourt (2020) report a small effect on care recipients symptoms in the short term (effect size -0.19, 95% CI -0.37 to 0.01; $p < 0.05$) compared to TAU but no effect over the longer term (effect size -0.18, 95% CI -0.56 to 0.21; NS). These findings were replicated for psychoeducation with small effects in the short (effect size -0.10, 95% CI -0.37 to -0.01; $p < 0.05$) and medium term (effect size -0.03, 95% CI -0.21 to 0.16; NS).

4.2.6 Institutionalisation

Walter & Pincourt (2020) did not find differences in institutionalisation for CBT at immediate time points (odds ratio 0.21, 95% CI 0.01 to 6.91; NS) and no studies examined these outcomes for CBT at later points. Effects were also not found for psychoeducation at immediate (odds ratio 1.05, 95% CI 0.57 to 1.93; NS) or late time points (odds ratio 1.27, 95% CI 0.64 to 2.51; NS). Each of these three analyses could include only a limited number of studies.

4.2.7 Effect modifiers

Walter & Pincourt (2020) used a meta-regression to explore whether study characteristics were associated with intervention effects. Randomised studies reported lower effects for improvements on care recipients symptoms compared to non-randomised studies but study quality scores were not associated with differing effects. Intervention effects on burden and depression were greater in samples with younger mean age of caregivers, and a lower proportion of female and spousal caregivers. Effects on anxiety were also greater for samples with younger mean age of caregivers. Where psychoeducation included active participation of caregivers, compared to provision of information alone, there appeared to be a greater effect across outcomes but the number of sessions and delivery to individuals or groups were not associated with effect.

Lee et al. (2020) do not report on effect modifiers through meta-regressions or sensitivity analysis.

Table 3. Systematic review and meta-analysis: Walter & Pinquart (2020)

Included studies		Inclusion criteria		Quality and Risk of Bias		Observation/notes	
<p>Number of studies: 280 studies, with 39 evaluating CBT and 115 evaluating psychoeducation</p> <p>Total number of patients: Not reported</p> <p>Publication year: 2020</p> <p>Mean care age: 62.1 years[^]</p> <p>Proportion female: 76.3%[^]</p> <p>Mean proportion partners: 53.7%[^]</p>		<p>Review period: Not reported</p> <p>Review purpose: To assess the effectiveness of dementia caregiver interventions on improving outcomes</p> <p>Included study designs: Randomised and non-randomised controlled trials where assignment was assessed not to lead to systematic between-group differences</p> <p>Included outcome measures: Pooled effect sizes (Hedges G) for burden, depression, anxiety, subjective wellbeing, symptoms of care recipient, institutionalisation</p>		<p>Tool: Four criteria scale (random assignment, no significant baseline differences, more than 10 participants per arm, less than 10% drop out)</p> <p>Risk of Bias: Summary of risk of bias ratings are not provided but are included in meta-regression.</p> <p>Adjustment for publication bias: Egger's test and a trim-and-fill analysis was used. Adjusting effect sizes for missing studies had a limited impact on results but did lead to improvements in care recipient symptoms losing significance.</p>		<p>The review included studies evaluating a wider range of interventions than the scope of this EAR (e.g. social support, case management). Only the results of studies evaluating CBT and psychoeducation are reported here.</p> <p>The review separates immediate and follow up effects. The mean time to data collection for immediate effects was 0.6 months and mean time to follow up data collection was 7.9 months.</p> <p>Meta-regressions were used to assess the impact of study characteristics. Minimal impacts were seen with effect sizes remaining small to moderate with adjustment.</p>	
Results							
Intervention		Follow up		Number of studies (participants)		Effect size (Hedges G or odds ratio) [#]	
Burden							
CBT		Immediate		26 studies (n=1,758)		ES: -0.37 (95% CI -0.49 to -0.24; p < 0.001)	
		Follow-up		8 studies (n=606)		ES: -0.32 (95% CI -0.58 to -0.05; p < 0.05)	
Favours CBT						Favours CBT	
Psychoeducation		Immediate		71 studies (n=6,301)		ES: -0.21 (95% CI -0.28 to -0.13; p < 0.001)	
		Follow-up		23 studies (n=1,872)		ES: -0.28 (95% CI -0.42 to -0.14; p < 0.001)	
Favours psychoeducation						Favours psychoeducation	
Depression							
CBT		Immediate		29 studies (n=2,215)		ES: -0.33 (95% CI -0.44 to -0.21; p < 0.001)	
		Follow-up		11 studies (n=913)		ES: -0.31 (95% CI -0.52 to -0.10; p < 0.01)	
Favours CBT						Favours CBT	
Psychoeducation		Immediate		50 studies (n=3,895)		ES: -0.23 (95% CI -0.32 to -0.14; p < 0.001)	
		Follow-up		17 studies (n=1,357)		ES: -0.26 (95% CI -0.42 to -0.10; p < 0.01)	
Favours psychoeducation						Favours psychoeducation	
Anxiety							

CBT	Immediate Follow-up	7 studies (n=457) 4 studies (n=318)	ES: -0.37 (95% CI -0.69 to -0.05; p < 0.05) ES: -0.34 (95% CI -0.75 to 0.07; NS)	Favours CBT Favours neither
Psychoeducation	Immediate Follow-up	6 studies (n=1,057) 2 studies (n=312)	ES: -0.24 (95% CI -0.54 to 0.06; NS) ES: -0.29 (95% CI -0.82 to 0.14; p < 0.001)	Favours neither Favours psychoeducation
Subjective wellbeing				
CBT	Immediate Follow-up	11 studies (n=1,034) 3 studies (n=447)	ES: 0.22 (95% CI -0.01 to 0.44; NS) ES: 0.35 (95% CI 0.03 to 0.66; p < 0.05)	Favours neither [£] Favours CBT
Psychoeducation	Immediate Follow-up	22 studies (n=1,395) 6 studies (n=423)	ES: 0.27 (95% CI 0.10 to 0.44; p < 0.01) ES: 0.35 (95% CI 0.08 to 0.62; p < 0.01)	Favours psychoeducation Favours psychoeducation
Symptoms of care recipient				
CBT	Immediate Follow up	13 studies (n=655) 5 studies (n=198)	ES: -0.19 (95% CI -0.37 to -0.01; p < 0.05) ES: -0.18 (95% CI -0.56 to 0.21; NS)	Favours CBT Favours neither
Psychoeducation	Immediate Follow-up	45 studies (n=3,900) 16 studies (n=1,075)	ES: -0.10 (95% CI -0.37 to -0.01; p < 0.05) ES: -0.03 (95% CI -0.21 to 0.16; NS)	Favours psychoeducation Favours neither
Institutionalisation				
CBT	Immediate Follow-up	1 studies (n=32) 0 studies	OR: 0.21 (95% CI 0.01 to 6.91; NS) NA	Favours neither
Psychoeducation	Immediate Follow-up	7 studies (n=934) 3 studies (n=541)	OR: 1.05 (95% CI 0.57 to 1.93; NS) OR: 1.27 (95% CI 0.64 to 2.51; NS)	Favours neither Favours neither
[^] across all studies, not reported separately for CBT and psychoeducation; [#] Hedges' g values of 0.15, 0.40, and 0.75 are typically considered small, medium, and large effect sizes; [£] The confidence interval on this finding is marginal and may be indicative of a small effect				
CBT: cognitive behavioural therapy, CI confidence interval, ES: effect size, n: number. NA: not applicable, NR: not reported, NS: non-significant, OR: odds ratio.				

Table 4. Systematic review and meta-analysis: Lee et al. (2020)

Included studies	Inclusion criteria	Quality	Observation/notes
<p>Number of studies: 26 studies, with 3 evaluating CBT and 5 evaluating psychoeducation</p> <p>Total number of patients: 3,906 participants[^]</p> <p>Publication year: 2020</p> <p>Mean care age: 60.5 years[^]</p> <p>Mean proportion female: 73.9%[^]</p> <p>Mean proportion partners: 46.0%[^]</p>	<p>Review period: up to January 2018</p> <p>Review purpose: To assess the effectiveness of psychosocial interventions on improving caregivers quality of life</p> <p>Included study designs: Randomised controlled trials that include health-related quality of life measures</p> <p>Included outcome measures: Pooled effect sizes (Hedges G) for improvement in health-related quality of life</p>	<p>Tool: Cochrane Collaboration Risk of Bias Tool</p> <p>Risk of Bias: Studies had low or unclear risk of bias across most outcomes. Three studies reported high risk of bias due to incomplete outcome data, issues with blinding participants or personnel, and selective reporting.</p>	<p>The review included studies evaluating a wider range of interventions than the scope of this EAR (e.g. social support, case management). Only the results of studies evaluating CBT and psychoeducation are reported here.</p> <p>The review was included as measures of health-related quality of life were disaggregated from other measures of subjective wellbeing.</p> <p>Details on length of follow-up are not reported.</p>
Results			
Intervention	Number of studies (participants)	Effect size (Hedges G) [#]	
Caregiver health-related quality of life			
CBT	3 RCTs (n = NR)	ES: 0.767 (95% CI 0.142 to 1.391; p = 0.016) Favours intervention	
Psychoeducation	5 RCTs (n = NR)	ES: 0.163 (95% CI -0.001 to 0.328; p = 0.052) Favours neither [£]	
<p>[^]across all studies, not reported separately for CBT and psychoeducation; [#]Hedges' g values of 0.15, 0.40, and 0.75 are typically considered small, medium, and large; [£]The confidence interval on this finding is marginal and may be indicative of a small effect</p> <p>CBT: cognitive behavioural therapy, CI: confidence interval, ES: effect size, n: number, NR: not reported, RCT: randomised controlled trial.</p>			

5. Economic evaluation

The START RCT included economic outcomes alongside information on clinical effectiveness and this data has been reported in three studies (Knapp et al. 2013, Livingston et al. 2014a, Livingston et al. 2020). Livingston et al. (2014a) was considered to be the most relevant for this review because it was the most recent study to present a cost-utility analysis. In this type of cost effectiveness analysis outcomes are measured in terms of quality-adjusted life-years (QALYs).

The cost-utility analysis by Livingston et al. (2014a) is summarised in Table 6. The analysis considered the cost-effectiveness of the START intervention in comparison to TAU from a health and social care perspective in the UK. A time horizon of 24 months was considered matching the trial period.

Costs were estimated using data on resource use collected in the START RCT (e.g. GP visits, inpatient and outpatient services). This includes use of health and social care services by carers and patients. Note that since the analysis adopted a health and social care perspective, it included some aspects that are not NHS funded or only partially, NHS funded. This may limit the applicability of the £20,000 per QALY threshold as this threshold relates primarily to opportunity costs within healthcare. This factor primarily affects the analyses where recipient of care costs were considered, as it was only this group that reported usage of non-NHS services.

Unit costs were sourced from standard sources such as NHS reference costs and the Personal Social Services Research Unit (PSSRU). QALYs were estimated using EQ-5D data collected in the trial with societal weights applied (Livingston et al. 2014a).

The results of the analysis were presented for two scenarios. In a scenario where only carer costs were considered, START was found to be more effective but more costly than TAU. The resulting ICER of £12,400 per QALY is below a threshold of £20,000 per QALY, indicating that START is cost effective. In a scenario where carer and patient costs were considered, START was found to be more effective and less costly than TAU. It was therefore considered to be dominant (cheaper and more effective).

Probabilistic sensitivity analysis results were presented for the scenario where carer and patient costs were considered. START was found to have a 67% probability of being cost-effective at a threshold of £20 000 per QALY. Probabilistic sensitivity analysis results were not presented for the scenario where only patient costs were considered. Therefore, the uncertainty around the conclusion in this scenario is not known.

In further sensitivity analysis, adjustments were made for imbalances in baseline characteristics in each arm of the trial. The mean ICER changed to £10,700 per QALY when only carer costs were included and £23,267 when both carer and patient costs were included. In this scenario, START was found to have a 50% probability of being cost-effective at a threshold of £20,000 per QALY when both carer and patient costs were included.

Table 6. Economic evidence

Study details	Study population and design	Data sources	Results	Quality assessment
<p>Author and year: Livingston et al. (2014a)</p> <p>Country: UK</p> <p>Type of economic analysis: Cost-utility analysis</p> <p>Note that the study also reports other forms of cost-effectiveness analyses using different outcome measures. We have focused on the cost-utility analysis as it is the most relevant to our decision problem.</p> <p>Perspective: Health and social care perspective</p> <p>Currency: UK pound sterling (£)</p> <p>Price year: 2009–10</p> <p>Time horizon: 2 years</p> <p>Discounting: Costs and benefits discounted by 3.5% per annum</p>	<p>Population The population in the analysis matches that of the population included in the START trial. That is family carers providing support at least once per week to people with a clinical diagnosis of dementia.</p> <p>Interventions The STRategies for Relatives (START) psychological intervention</p> <p>Comparator Treatment as usual (TAU)</p> <p>Study design Cost-effectiveness analysis conducted as part of the START trial.</p>	<p>Source of baseline and effectiveness data: Baseline demographics of carers and patients were collected within the START trial. Baseline estimates of quality of life and cost were also captured.</p> <p>Effectiveness was captured through differences in the Hospital Anxiety and Depression Scale (HADS) over time in each treatment arm (START and TAU). For the purposes of the cost-utility analysis, the effectiveness measure of most interest was differences in quality of life over time as measured by EQ-5D (see quality of life section below for more details).</p> <p>Adverse event data was not collected as part of the trial as it was judged that carers being unwell would not be due to the therapy being received.</p> <p>Source of resource use and cost data: The cost of the START intervention was estimated from therapist time required to deliver the intervention as well training and supervision time. Relaxation CDs used as part of the intervention were costed at market rates for copying and delivery.</p>	<p>Base case results</p> <p>Scenario with carer costs only</p> <p>Incremental costs (95% CI): £372 (–£189 to £933)</p> <p>Incremental QALYs (95% CI): 0.03 (0.00 to 0.06)</p> <p>ICER: £12,400 per QALY</p> <p>Scenario with carer and patient costs</p> <p>Incremental costs (95% CI): -£1,471 (–£10,909 to £7,968)</p> <p>Incremental QALYs (95% CI): 0.03 (0.00 to 0.07)</p> <p>ICER: Dominant</p> <p>Sensitivity analysis Results of probabilistic sensitivity analysis were presented for the scenario with carer and patient costs. START was found to have a 67% probability of being cost-effective at a threshold of £20 000 per QALY.</p> <p>In a sensitivity analysis, trial results were adjusted for relevant predictors of missing</p>	<p>Applicability The study was deemed directly applicable as it considered a UK NHS and social care perspective.</p> <p>However, note that the inclusion of social care costs and benefits may limit the applicability of the £20,000 per QALY threshold since this threshold relates primarily to opportunity costs within healthcare.</p> <p>Limitations The analysis was generally considered to be of high quality but some limitations were identified:</p> <ul style="list-style-type: none"> • Authors note the possibility of response bias as people with more difficulties might have been more likely to participate in the trial • Authors also note that the trial was not powered for the economic evaluation, which may account for the non-significance of differences in economic outcomes • Analyses referring to the £20,000 per QALY threshold include some costs and benefits, which are not NHS funded (or only partially, NHS funded). This may limit the applicability of the £20,000 per QALY threshold.

Study details	Study population and design	Data sources	Results	Quality assessment
<p>Potential conflict of interest: During the study, one of the authors received personal fees, grants, and other payments from GE Healthcare, and grants from Lundbeck, outside the submitted work.</p> <p>All other authors declared no competing interests.</p>		<p>Use of health and social care services by carers and patients was monitored as part of the trial (e.g. GP visits, inpatient and outpatient services). Service use was captured at 9-12 months and 21-24 months. Costs for months 13 to 21 were estimated by interpolation from data obtained at 12 and 24 months to generate costs for the full period.</p> <p>Unit costs for service use were sourced from standard UK costing sources – NHS Reference costs and the Personal Social Services Research Unit (PSSRU).</p> <p>Source of quality of life data: Quality of life estimates were based on EQ-5D data collected over the trial period. Quality-adjusted life-years (QALYs) were estimated using the EQ-5D data with societal weights applied.</p> <p>It is not clear whether in-trial survival data or other survival estimates were used as part of the QALY calculation.</p>	<p>data. This gave similar results to the base case with START found to have a 67% probability of being cost-effective at a threshold of £20,000 per QALY when both carer and patient costs were included.</p> <p>In further sensitivity analysis, adjustments were made for imbalances in baseline characteristics in each arm of the trial. The mean ICER changed to £10,700 per QALY when only carer costs were included and £23,267 when both carer and patient costs were included. In this scenario, START was found to have a 50% probability of being cost-effective at a threshold of £20,000 per QALY when both carer and patient costs were included.</p>	<ul style="list-style-type: none"> • Approach used for including survival estimates in QALY calculation are not clearly reported. • Probabilistic sensitivity analysis were only presented for scenarios where both carer and patient costs were considered
<p>Abbreviations QALY: quality-adjusted life year; ICER: incremental cost-effectiveness ratio; EQ-5D: EuroQol five-dimensions questionnaire; RCT: randomised controlled trial; START: STRategies for RelaTives; TAU: treatment as usual; HADS: Hospital Anxiety and Depression Scale</p>				

6. Organisational Issues

During discussions with the HTW Assessment Group, a number of relevant organisational issues were highlighted and experts were prompted to reflect on these questions during review. In addition, two relevant studies addressing organisational issues in the delivery of the START programme were identified in the systematic review (Amador et al. 2021, Lord et al. 2017).

Psychological interventions for carers of people with dementia could be implemented at various stages through health and social care pathways. The secondary evidence included in this review did not consider the timing of intervention in their analyses (Lee et al. 2020, Walter & Pinguart 2020). The START trial recruited most participants as dementia was being diagnosed (Livingston et al. 2013) and this was seen as appropriate by most participants (Sommerlad et al. 2014). However, interventions could also be provided at later stages of the pathway. Experts commented that delivery within a specified period around diagnosis may facilitate delivery. Similarly, it may also be desirable to identify subgroups of carers who would particularly benefit from intervention. Studies included in this review did not generally require participants to have a diagnosis or reach a cut-off score for anxiety and depression. However, the START study did report results for a sub-group of patients who were above cut-offs indicative of depression at baseline. The intervention reduced the number of people in this group above cut-off at follow-up compared to TAU and this suggests that offering START to carers with significant depression symptoms may be appropriate (Livingston et al. 2013, Livingston et al. 2014a, Livingston et al. 2020). Experts had varying views on these issues. Some felt that there was an equity and social justice case to provide the intervention to all carers, as well as a preventive role. Whereas others suggested this approach would not be feasible and subgroups of people who could benefit most would need to be identified. Suggestions on these subgroups were based around carer's with higher levels of symptoms or who had greater distress associated with caring.

Experts highlighted that consideration of other characteristics is needed. The START trial recruited a sample with around 20% of people being from ethnic minority groups. There is some suggestion from the study findings that people from ethnic minority groups found the intervention less acceptable and had lower completion rates (Livingston et al. 2013). Experts supported this view and indicated that work is ongoing to ensure that the manual and delivery of the programme is appropriate for people from different ethnic backgrounds. Experts from the START trial team highlighted that this has been completed for people from South Asian communities, with adaptation and translation into Urdu. Further, experts highlighted that this type of programme can be heavily reliant on literacy skills and this may present problems, especially in older populations. Many carers in Wales may be most comfortable with delivery of the intervention in the Welsh language and this should also be considered.

Finally, implementation of psychological interventions for carers of people with dementia in Wales may pose workforce issues. START has primarily been delivered by psychology graduates and recruitment within these roles would be needed if they were rolled out more widely. Graduate therapists would also need supervision by clinical psychologists and appropriate support structures would need to be put in place during implementation. Experts commented that it is difficult to predict whether the workforce demand would be met. They highlighted that resources for psychological interventions are currently pressured but also that there is a large pool of psychology graduates within Wales, with eight universities providing undergraduate psychology courses. This type of graduate therapist role sits within the pathway required for psychology graduates to progress to clinical psychology doctorates and demand for the roles is high. There is also the possibility that specialist dementia nurses could be trained in delivery of the START programme and this has been trialled successfully across the UK, including in Port Talbot (Lord et al. 2017). In addition, a small-scale study in England has suggested that delivery of START could be supported by voluntary sector (Amador et al. 2021). Both of these approaches could expand the potential workforce available to deliver the intervention and ease the burden of delivery on local health boards. Experts suggested

that, ultimately, whether there are sufficient resources is likely to come down to political will and whether the government and health service is willing to provide resources to support implementation of services for carers.

7. Patient, carer and family perspectives

7.1 Evidence from published sources

One study that looked at carers' experience of START was identified in the systematic review (Sommerlad et al. 2014) and was completed as part of the RCT of START (Livingston et al. 2013).

During the trial, Sommerlad et al. (2014) asked participants to complete questionnaires on their experience of receiving interventions. This was done during the 24-month follow up and was completed by post or in an interview with a researcher. Seventy-five responses were received and these were then transcribed and analysed using a thematic framework approach. The authors reported that four broad themes were seen in the responses: important aspects of the therapy, engagement with the therapy, unhelpful aspects and improvements, and appropriate timing of the intervention. Participants appeared to value the diverse components of the intervention and indicated that they still use content and refer back to materials. There was variability in what was seen as unhelpful about the intervention. Some participants suggested more sessions, a follow-up, or more involvement of the person receiving care. Others suggested that focusing on the likely future course of the illness and worsening severity should have been explored more. Regarding timing, most participants received the intervention around the time of diagnosis and felt this was the right time.

7.2 Evidence from Alzheimer's Society focus groups

HTW collaborated with the Alzheimer's Society to collect evidence on the perspectives, insights and experiences of people with dementia and the family and friends who help to care for them on the impacts that caring may on carer's mental wellbeing. The Alzheimer's Society (AS) invited HTW researchers and members of the PPI Standing Group to take part in two focus groups, one attended by people with dementia and one attended by people who care for people with dementia, in May 2021. These focus groups took place as part of an ongoing series of monthly meetings held by AS with their Dementia Voices community and were attended by members of AS's Dementia Voices and AS staff. Additionally, AS collaborated with HTW on a questionnaire that was disseminated to their wider patient and carer community and provided HTW with written testimonies from individuals who wished to take part in the focus groups but were unable to do so on the day.

This section summaries the findings of both focus groups, the questionnaire and written testimonials. Both focus groups had 15 attendees (30 in total). Forty-two responses to the questionnaire were received as well as two written testimonials. AS provided HTW with transcripts of the discussions from both focus groups and a collated spreadsheet of the responses to the questionnaire, which HTW have used to inform this report.

7.2.1 Focus group for people with dementia

This focus group met on 26 May 2021. Attendees were given three questions to consider for discussion:

- 1) How do your family and friends meet your needs, for example your mental wellbeing or things you can't do for yourself at home?
- 2) What impact do you think this has on your family and friends?
- 3) How necessary is it for you that you have family and friends to do this, rather than rely on paid-for services?

These questions were pre-agreed with AS staff and circulated one week before the date of the focus group to give attendees time to consider their responses. After a short introductory talk, the focus group broke up into two break-out groups to discuss these questions before coming back together to feedback on emerging themes.

7.2.1.1 Question 1: How do your family and friends meet your needs?

Attendees responded that maintaining their independence, keeping active and not 'overly-burdening' family and friends are important to them. The majority of attendees live at home with family, but a significant number reported that they live alone and are visited by friends and family. The minority of attendees reported living alone and not receiving frequent visits.

Levels of independence varied, from requiring full daily support *"my wife is always with me. I need to use a frame; she takes me out shopping because I need exercise"*, to support with specific tasks, such as dealing with paperwork *"I struggle with bills - my family live in Yorkshire and I am lucky I have friends who help me"*, *"I have speech issues which get worse on the phone"*, safety *"I do daft things – like I don't lock the front door"*, *"things like light bulbs as I'm quite ham-fisted so not allowed to do that sort of thing"*, driving *"my wife has to drive as I lost my licence. I try to do bus and train as much as I can"* and meal preparation *"My wife makes me ready meals – I find them quite easy"*, as well as emotional support *"They talk and listen – that's a big point"*, while some reported maintaining nearly full independence *"I'm still quite able. I don't require a lot"*. Attendees discussed the importance of family and friends in providing motivation to undertake daily activities *"my grandson comes to stay at the weekend and that makes me cook dinner, gives me motivation. I need someone to say 'what time are we eating Nan'"*, *"It is so easy to sit in a chair and do nothing"*, *"I was finding it lonely but I came across a friend with nothing to do so he comes out twice a week and takes me out like to play golf"*.

Attendees expressed a reluctance to ask for help *"If I am desperate for something then my son is down the road and I will ask him, but I avoid it as much as possible"* as asking for help can have a negative impact on their wellbeing, *"I loose elements of self-esteem when I need to ask for help from others."*

7.2.1.2 Question 2: what impact do you think this has on your family and friends?

Attendees confirmed that part of their reluctance to ask for help is out of concern for the impact it may have on family and friends *"I want to be independent, I don't want to depend on my wife and kids - they have their own lives and deserve to live it"*, *"She is always with me and she needs a break"*, and that this can have a negative impact on their own wellbeing *"I feel frustrated for myself and for her"*, *"I feel guilty about asking for help as he is so much older than me"*, *"I feel I can't interrupt during working day"*. Attendees identified that it is usually one family member who becomes primarily responsible for their care *"My two sons don't live too close. It's all on my wife."* and that this can be difficult *"it's putting strain on my relationship with my wife. I'm very demanding. She has her own problems but mine take precedence and I've no patience"*, particularly when there are many other additional responsibilities to consider *"My wife's mother is showing signs of dementia which is starting to cause an issue with me as I've been used to having my wife regularly supporting me"*. Attendees agreed that caring can be *"very difficult"* for the carer and discussed how the nature of the personal relationship plays a part *"You don't want your kids to come and see you and do that as a burden"*, *"I worry about my friends sometimes - am I putting too much on them? I'd rather struggle on my own than put on my friends. I worry about crossing that line from asking a friend for help now and then to them becoming my carer"*, as the person providing the care is not often termed 'a carer' by both themselves and the person they provide care for, *"I don't think myself as his carer; I am his partner"*.

Attendees discussed the impact that their dementia can have on their relationships and how that can affect their wellbeing, *"(my husband and I) our lives are overlapping now. We have lived separate*

and independent lives and now they are overlapping which I feel guilty about as it's me asking or needing support to continue to be independent", "a time will come when she won't be able to cope with me and I am afraid I may have to go into a home. I don't want to and I know she wouldn't want me to go into a care home but she has got to think of herself. She isn't too well herself and I try and help as much as I can but I just don't want to depend"

7.2.1.3 Question 3: how necessary is it for you that you have family and friends to do this, rather than rely on paid-for services?

Attendees suggested that there is little support available to them from paid-for or professional services. When asked specifically about support from doctors and other healthcare professionals, attendees stated that no support has been offered to them and noted that *"I don't think there is enough support at all. It's something that needs to be looked at."* Attendees highlighted that the sources of support available to them and their families are from not-for-profit organisations, such as volunteer groups and day centres run by charities. Attendees spoke of attending events such as singing in day centres (pre-COVID-19 pandemic) and local churches, which were described by one attendee as *"a big family, with lots of people willing to help in any way they could – lifts to hospital, or to come and sit down with me"*,

Some attendees said that they have weekly visits from paid-for carers, but the decision to do so was more to provide some respite for family from caring responsibilities. Attendees described a preference for family over paid-for carers, *"family know you, your antics etc and outside carers are limited – they're on the point of leaving your property by the time you've offered them a cup of tea and put the kettle on"*, *"There's nothing like your own family as they know everything about you – all your quirks"*

Additionally, attendees spoke favourably on the role that technology can play in maintaining their independence and keeping up their motivation, *"Alexa is my best friend and I have a computer diary - tech helps me keep connected and motivated, Jigsaw puzzles, word games and reading keep my mind busy, my motivation is to keep busy. If I keep my brain busy then I am slowing the disease"* and in particular the role of music, *"Music is for me the key – music in lots of different forms"*, *"Family bought me Alexa. I go on UK Gold and watch 50s and 60s music and singalong"* particularly during the COVID-19 pandemic *"we do singing over Zoom"*.

7.2.2 Focus Group for Carers of People with Dementia

This focus group met on 28 May 2021. Attendees were given three questions to consider for discussion:

- 1) How does caring for a person with dementia affect your life with your family and friends?
- 2) What impact does caring have on you?
- 3) What support would you like with caring that you don't have?

As before, these questions were pre-agreed with AS staff and circulated one week before the date of the focus group to give attendees time to consider their responses. After a short introductory talk, the focus group broke up into two break-out groups to discuss these questions before coming back together to feedback on emerging themes.

7.2.2.1 Question 1: How does caring for a person with dementia affect your life with your family and friends?

Attendees advised that the responsibility of caring for a family member with dementia predominantly falls on one person. This can put strain on family relationships, particularly where there are siblings *"When it gets hard I think, why can't my sisters help out more? I have my own husband and children and yet it's only me looking after our mother full time"*, which can lead to negative emotions about family members, *"I feel cross and I want to say something,"* as well as making life for the carer very

isolating as they often lose relationships as a result, *“It was very lonely to be a carer. Most of our friends dropped away.”*, *“Friends withdrew. I felt on the outside, looking in on things”*. Friendships in particular become difficult, *“Some friends have been very helpful, but others don’t understand”*, *“Friends came and went – they didn’t understand”* and the loss of friendship for the person with dementia was difficult for the carers to watch *“my wife is still my wife; I want to tell her friends to come and see her because she is still there and it hurts me that they don’t, particularly when they stopped sending her a card on her birthday”*

Attendees advised that the kind of support and care they provide changes with disease progression, *“the type of care you’re giving varies; at first it’s banking and doing the shopping, and then later you are your parents’ parent”* and this impacts on the carer’s life in different ways *“I used to go out and present workshops, that sort of thing, and now I’m confined to my home 24/7”*. Attendees described living completely different lives when their loved one’s dementia become more progressed, *“I had to give up work. I had to give up outside life entirely”*, *“being a carer changed my life considerably”* and in some cases the impact was severe *“it cause me mental health problems, I couldn’t cope”*, *“I didn’t have support. I ended up in crisis and only then got support.”*

Attendees also noted how other life concerns can add to the responsibility of caring, *“I tried to keep ahead of the game, but when you’re carrying lots, the little problems can seem a lot bigger”* and that a move into a care setting, such as a care home, does necessarily make life as a carer easier, *“it doesn’t take the pressure off, I have carers from the home calling me all times of the day, they constantly lose her clothes and glasses and I have to sort it all out”*.

7.2.2.2 Question 2: What impact does caring have on you?

Attendees discussed impacts such as the emotional difficulties of getting a dementia diagnosis, *“When she was diagnosed I was heart-broken and all the way through the disease”*, *“Basically, when my wife was diagnosed, she couldn’t accept the diagnosis for a couple of years. It affected me mentally”*, sleep, *“I started not sleeping. I got anxious, and now I’m on medication. Still not sleeping.”* Experiencing the loss of the person to the dementia, *“I miss the person they were, we always loved to chat and used to have great conversations”*, feelings of guilt *“I constantly feel guilty, about my mother and then about the time I take away from my husband and my children to look after her”*, the mental exhaustion *“I get more tired. You have to concentrate all the time and I spend my days anticipating his needs”* and the need to support other family members, *“My father died many years ago and my sister and brother I cared for through it had different issues. I had to give time to them so I didn’t have much time for me.”*, *“my children all react differently, but I have to look after them too”* which often leaves carers with no time for themselves.

All attendees noted that they choose to take on this caring role and don’t tend to think of themselves as ‘carers’, *“Its’ done with love, I don’t think myself as his carer, I am his partner”*.

Attendees advised that there were also significant impacts of bereavement *“I was a carer for the biggest part of my life. When it came to an end, I didn’t really speak for 12 months, the impact was so great on me. I had counselling. It’s 7 – 8 years on and I still need counselling occasionally.”* They described how it is often at this time that the impacts from caring stored over the years become evidence in their lives, *“There’s things I know now, I didn’t know then. I have panic attacks now – I didn’t used to.”*, *“When the person passes, you’re left with lots of emotion you don’t realise that you’ve got”* and that the effects of caring last beyond the point where the loved one has passed, *“Things happen that bring you back to those times. My mother died within 6 months, in hospital. I went through safeguarding. Being a carer never leaves you”*, *“it’s a constant battle. No surprise that people who have been through the mill of caring often say, as I do, that I wish I’d known then, what I know now”*

Question 3: what support would you like with caring that you don't have?

Most attendees only referred to attending counselling after the loss of their loved one to dementia and not during their time caring for them.

Better education for healthcare professionals to enable them to offer support that reflects what people go through was proposed, *“the GP that diagnosed my wife tried to be caring but struggled when he realised that we knew more about my wife and her dementia than he did. We moved to another GP in the same practice who had dementia care experience and the difference it made was huge”, “I had a social worker who didn’t understand sundowning. I would have liked someone more understanding – one even tried to wake mum up when she was in the end of life”, “when my wife was diagnosed with dementia I was given a big pack of leaflets. A social worker came and told us ‘you don’t need anything’ and gave us more leaflets. 4 or 5 social workers came like that. Never had the same social worker till the last year.”, “I had a lot of trouble with social services – they weren’t willing to meet me half way- that was very hard”*

Regular contact with support services was also proposed, *“I’d like someone I could talk to once a week and not only in an emergency”, “Having someone as a regular contact any day of the week so that I could talk and feel I’m not trying to make decisions on behalf of my wife alone”,*

Attendees also expressed a wish to be listened to and feel that their voices are heard, *“I want people to listen more and be more aware of what’s going on and to be more hands on”, “I had a night-staffer arranged via the crisis support, but we became friends as we used to sit and have coffee nights – just having normal chats like other people do in the day time”*

Attendees reported being able to access support through not-for-profit organisations, *“we were sent to The Hub, a place in Belfast. They sat down with my wife and talked in one room. I went and sat with a social worker and talked in another room. It was great – but only an 8 week course. We need more and for longer”, “I just want people to be aware of these issues for carers and to listen to carers.”* and discussed how physical exercises, such as joining walking groups and yoga can help, as can keeping busy.

Lastly, attendees spoke of the importance to further funding into dementia research, *“I want to put pressure on the government – how come dementia is so far away from any cure or control to slow it down? It’s very important more and more people are getting dementia, even people in their 20s and 30s”, “put pressure on the government. 14 months ago there was no Covid vaccine – now we’ve got one. 30 years ago we knew about dementia – and what have we got?”*

7.2.3 Questionnaire for Carers of People with Dementia

A questionnaire on the potential impacts that caring for a person with dementia may have on carer’s mental wellbeing was co-produced by HTW and AS and hosted online by AS. The questionnaire posed 8 questions:

- 1) Are you a person living with dementia or a carer for someone with dementia?
- 2) What activities do you either need support with or provide support for?
- 3) How often do you require or provide this support?
- 4) What current support do you receive from Health and Social Care Services? For example, from your Local Authority or Social Services?
- 5) Do you receive support from any other organisations who provide activities such as support groups, befriending?
- 6) Do you think the caring role impacts on that persons daily life?
- 7) Do you think carers for people with dementia need specific support to look after their mental health?
- 8) What one thing would make it easier for a carer for a person with dementia?

The questionnaire was live for one week and 42 responses were received. These responses were collated by AS and shared with HTW for analysis.

Of the 42 respondents, 15 identified themselves as a person living with dementia. Two respondents advised that they are carers for more than one family member with dementia, two are carers for family members who live in care homes and two respondents advised that they were carers of family members who have passed. The remaining nine respondents advised that they are the primary carers for one family member with dementia.

Respondents confirmed dementia diagnoses of Alzheimer's, Parkinson's and Post Cortical Atrophy (PCA).

One respondent commented *"As a person living with the immediate impact of ever decreasing cognitive abilities and to some degree my physical abilities following closely behind, I am constantly aware of the pressure on my carer, who continues her care for me without complaining"* in response to this question.

Respondents advised that the forms of care required or provided included personal care, meal preparation, administering medication, undertaking shopping, providing support with hobbies and activities (such as gardening, attending singing groups and art groups and generally keeping active), daily administration (making appointments, undertaking paperwork such as bills and utilities, legal documents, reading letters etc), supervising trips outdoors, finances, translating or speaking on their behalf if or when they are unable to communicate sufficiently, mobilising, everyday tasks, ensuring their safety (including constant monitoring and falls prevention and domestic tasks such as cleaning and washing. *"I care for my wife 24/7. She can't cook, shop, use money, write properly, see to her personal care or organise & use her medication. She has no hobbies despite trying a few subjects except enjoying looking at her garden"; "My husband is now unable to wash or dress himself, and I have support with this on 5 mornings a week"; "continual monitoring to ensure my husband doesn't get out of the house by himself as he has no idea of where he is and to make sure he is safe within the house and garden in terms of stairs and steps- falls prevention"*

Six of the respondents who were living with a dementia advised that they are currently able to meet their own needs but recognise that as the dementia progresses, they will become more dependent on support from others *"at this moment in time I try to do everything I can whilst still able but shortly in the future I will need help in properly all the above"*

One respondent reflected further that *"The unparalleled and moreover unpaid support that I require to function daily, albeit in a limited way, if not for the care and support my wife gives me; this is given in an unlimited amount not requiring proofs of my needs. I don't have to meet any criteria to receive her unparalleled ability to attend to my needs"*.

Of the 42 respondents, 19 said that they require support or provide support daily from once to several times a day, while 18 respondents advised that they require or provide support continuously. The remaining 5 respondents required or provided support once a week or less.

In response to the fourth question (What current support do you receive from Health and Social Care Services? For example, from your Local Authority or Social Services), 28 respondents advised that they do not receive any support. The remaining 12 respondents (excluding the two carers who continue to support their family member who lives in a care home) advised that they receive support such as visits from an occupational therapist, respite care and home equipment, reductions in council tax, carers who visit the home weekly and classes run by local authorities (*"I have joined a Caring Together support scheme run by the local Council which is available to look after the person with dementia in the event of an emergency, such as the carer being taken ill"*). One respondent reported receiving a carer's allowance *"I get a carer's allowance, incontinence products, grant towards housework cleaning, regular contact through the carers team via phone, email & Zoom calls. Offers to join carer's groups, regular emails offering a wide range of activities, courses for carers"*

One respondent wanted to note in particular the difference in the nature of care when it is provided from family, saying *"(I am not) required to give proofs of my needs ,or (required) for any need to*

meet some form of criteria to be met before I can be considered to have my needs to be met (by family; unlike) by an institution that seems to have lost the meaning of care and any attributes pertaining to care in the community”.

Twenty-six respondents advised that they receive support from organisations outside of Health and Social Care Services, including community projects (such as art and day centres), charities (such as Alzheimer’s society, the Carers Association, the Royal voluntary service, Age UK), local support groups, befriending other carers through networks and paying for private care support. Support offered ranged from weekly phone or video calls to attending classes, programs and day centres.

All 42 respondents advised that they felt that providing support/undertaking a caring role impacts upon that person’s life. When asked to reflect further, respondents advised that *“the caregiver doesn’t think of themselves but only person with dementia”*, and that this can *“effect(s) all relationships... the caregiver’s health suffers (and) also (their) mental health”*. Carers advised that their caring role can take up most of their time leaving little time for anything else, *“24/7 role. My business and hobbies severely reduced”*, *“(it is) hard to look after a parent and have a life as you always have to be available”*, *“my life revolves around looking after my husband, as he can do very little for himself anymore. I feel that I rarely get a break, and when I do meet friends, I have to leave him in front of the TV (which he loves)”*, advising that *“this is a whole new way of living for both the person with dementia and their carer”*. Respondents advised that the emotional impacts can be distressing for carers, *“The emotional stress has a telling effect on your day to day life, plus of course the psychical impact on you from the additional work load”* and that the impacts of providing care on carers are broad and wide-reaching *“A carer carries many worries and issues”*, *“affects all of life, restricting almost all activities and occupying quite a lot of the night”* that often encompasses a requirement to be both physically and mentally present at all times *“Mental and physical exhaustion, being woken up two or three times a night, constantly trying to find things that have been hidden, trying to persuade them to get washed/dressed/undressed etc. Trying to reassure and find ways to maintain calm, continually on guard in case of accidents, falls etc”*, *“My role as a carer was 24/7 leaving little or no time for myself.”*

One respondent described the act of providing care in the following way; *“being a carer means 'living the life of the cared for, so that the carer herself /himself literally has not got a life of their own in terms of 'Me' Time, leisure, socialising, medical health care, mental health care, physical health, respite, holidays, personal care”*,

Carers noted in particular that the burdens and effects of caring are not often expressed until after the carer has lost the person they were caring for, *“I cared for my wife 24/7 for eight years during which I had no life of my own. My life was given over to caring. After she died it took nearly two years to recover my health. I was completely washed out”* and that *“Caring is often seen as either a family responsibility therefor not given recognition for the massive contribution the unpaid carers make or seen as a stopgap or low skilled job that people drift into and not given its true value low pay poor working conditions all lead to an undervaluing of paid carers roles which inevitably leads to a lack of value for those being cared for”*

Twenty-seven respondents answered that they do believe that carers need specific support to look after their mental health, advising that carers need *“someone who was a carer to truly empathise”*, *“Someone to befriend them. It is such a lonely role - my partner has been subsumed by dementia - he is a different person from my previous best friend”* as caring *“Is not the easiest job, can be very hard emotionally on times”*,

Regarding their mental health in particular, carers noted that *“My mental health has definitely suffered as my husband's Alzheimer's has worsened. On some days I find it difficult to cope at all”*, *“I think professional and medical staff should reach out to carers and pay attention to the needs of carers even when they do not seek these help because in the run of the mill , carers forget about themselves, until they reach breaking point /burn out.. Very often, carers are ridden with shame,*

guilt, sadness/depression, incrimination, blame and depreciating self worth. They turn inwardly and impacts negatively on their mental well being enormously” and additionally note that “caring for a loved one with dementia takes an emotional toll which is quite different to other illnesses and conditions” thereby leaving carers with specific needs.

The remaining 15 respondents answered “I am not sure” to this question, advising that it can depend on disease progression and changing circumstances “I think this very much depends on the individual concerned. For me I have no mental health problems as a result of this situation. We are both retired anyhow, so I always say that it's not like I have anything else to do, is it? Seeing my wife happy & knowing that she is getting the best care I can give her is enough. I know & understand things will get harder as things progress & that is when I will ask for further help, once I am struggling to cope” and noting that no two carer experiences are ever the same “I think it depends on the person there circumstances, the degree of and stages of dementia the person is at as well as friends and family support. It's not a one size fits all approach and changes as the disease progresses and the carers needs change as there health and circumstances change”. Respondents commented that it can also depend on the personal nature of the carer “I think anyone in a caring role needs to look after their mental health, but not sure about specific support, they just need to make sure that they find a way to take time out for themselves & do the things they enjoy”.

The majority of respondents cite *having someone to talk to who listens* as a primary unmet need that carers have that would make caring for someone with dementia easier, “To have a care system that is easy to get hold of and they listen and act”, “Having a friend to talk to”, “Someone to talk to on a regular basis without feeling I am a bother or intruding”, “To be listened to and at least be met half way.”, “To be able to discuss how you feel, to be able to air your concerns about the person with dementia”, “It would make it easier for a carer if when things get too much for them to cope with the pressure, they could have easy access to professional help to talk things over face to face.”, “Having someone to share the care, and to discuss that care, with. In my case I did have my son available in the same house, but he had his own life and work to attend to. I also had the chance to discuss the situation with my daughter who lives elsewhere. I think the situation of a carer who has no close family must be very difficult. A person allocated by social services or similar who understands the carer's situation should be available as needed, so that the carer feels less alone!”

Second to this was having a better understanding of dementia and what carers go through and increased empathy, “support, safety, empathy, knowledge of the disease”, “support from others, understanding the problems and the impact of such problems, awareness”, “for me, Over the years I have cared for my husband, I would have found it easier and facilitating and kind, if professionals, NHS staff and consultants UNDERSTOOD”, “Extra help without a constant fight”, “Better informed social workers”, “Follow up by the doctor”, “respect”.

Specific types of support requested by respondents include greater support from healthcare services “More help from the LA, such as assistance during the day that I am not having to pay for. More Day Care centres.”, “radical change to the NHS and the awareness of how this horrible disease effects those who are suffering”, “a return to a situation whereby normal social interaction would safe and legal”, “maybe an easier, quicker system of applying for & getting help”, “more day centres for the person with Dementia, that would give the carer a much needed break”, respite care “being able to walk away from caring for a specified time, a week, in the knowledge that the person with dementia is being well cared for in respite. If the person is wife/husband it is the most difficult thing to do, I didn't take that length of break and it nearly ruined my life”, “A bit of time for themselves”, “respite, both short and long term” and financial support, “A lot of carers are of pension age and do not get the carers allowance, if you are under pension age they can get carers allowance and that can be a lot of help with bill's and so on”, “I think if family carers where paid by the government for their professional care, it would save more money for care in the community required at a later stage”.

7.2.4 Patient and Carer Testimonials

Two written testimonials were received to supplement the findings of the focus groups. These can be found in full in Appendix 5.

8. Conclusions

Evidence on the effectiveness and cost-effectiveness of the START programme is available from one RCT conducted in the UK. There is also a large body of evidence on the effectiveness of psychoeducation and cognitive behavioural approaches that supports the plausibility of the findings seen in the START trial.

A series of studies that report on a UK-based trial of the START intervention were identified with differing findings across outcomes. In particular, START appears effective in reducing symptoms and cases of depression and improving the quality of life of carers compared with TAU, but there was no difference in symptoms or cases of anxiety, quality of life for recipients of care, or time to placement in residential care. Follow-up of up to six years suggests that improvements can be maintained over time and that the intervention has long lasting impact. Economic evidence from the START trial suggests that, in the short term, this intervention is cost-effective if only carer costs are considered and cost-saving if the costs of both carer and recipient of care are included. As benefits have been shown to be maintained over longer follow-up, these findings may become more favourable over the long term.

Recent meta-analyses on the effectiveness of similar interventions are available. A recent comprehensive review of evidence on CBT and psychoeducation interventions was identified as the highest priority evidence based on our selection criteria. The review suggests that interventions of this type have small to medium effects on reducing the burden felt by carers, depression, and wellbeing compared to TAU. Results for anxiety were more equivocal and interventions did not appear to improve care recipients symptoms over the longer term or reduce placement in residential care. In addition, a further review that focused on HRQoL was identified and suggested that intervention of this type could lead to improvements on these measures compared to TAU.

There are a number of organisational issues may need to be considered during development of HTW guidance and implementation. Decisions may be needed about where Interventions would be best placed within dementia pathways and providing intervention to subgroups of patients may be more feasible than a universal approach. In addition, there may be workforce constraints with a need for graduate therapists working under supervision of clinical psychologists. Several published studies and input from groups from AS provided information on patient, carer, and family perspectives. This evidence supports that there is a significant burden placed on the mental health and wellbeing of people who provide care for a person with dementia. Participants in the focus group noted that carers receive very limited support and have few avenues to speak about the issues they face away from situations where the person with dementia is the focus of health and social care providers. Qualitative studies suggest that participants found START helpful and valued its varied content, although some improvements were suggested.

9. Contributors

This topic was proposed by Lisa Trigg (Social Care Wales).

The HTW staff and contract researchers involved in writing this report were:

- J Washington, Information Specialist – literature searches & information management
- G Hopkin, Senior Health Services Researcher – clinical author
- M Prettyjohns – economic author
- A Evans, PPI Officer – PPI lead
- K McDermott, Project Manager – project management
- L Elston, Senior Health Services Research – quality assurance
- T Winfield, Senior Health Economist – quality assurance

The HTW Assessment Group advised on methodology throughout the scoping and development of the report.

A range of clinical experts from the UK provided material and commented on a draft of this report. Their views were documented and have been actioned accordingly. All contributions from reviewers were considered by HTW's Assessment Group. However, reviewers had no role in authorship or editorial control, and the views expressed are those of Health Technology Wales.

Experts who contributed to this appraisal:

- S Abraham, Consultant Geriatrician / Assistant Medical Director, BCUHB
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- J Schneider, Professor of Mental Health and Social Care, University of Nottingham
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11. Evidence review methods

We searched for evidence that could be used to answer the review question: What is the clinical effectiveness and cost effectiveness of the Strategies for Relatives (START) programme aimed at improving the mental health of carers of people with dementia?

A systematic literature search for evidence was undertaken and was last updated on 26 August 2021. Appendix 3 gives details of the search strategy used for MEDLINE. Search strategies for other databases are available on request. The initial criteria used to select evidence for the appraisal are outlined in the protocol in Appendix 1. These criteria were developed following comments from the HTW Assessment Group and UK experts. Initially, the selection criteria for this appraisal included any psychological intervention using a cognitive-behavioural therapy or psychoeducational approach. Through the appraisal, the HTW Assessment Group judged that the initial criteria were too expansive to produce meaningful guidance and the scope was amended to focus on the START programme only. The HTW Assessment group also considered a second intervention, the WHO iSupport programme, for inclusion, but our literature searches did not identify any relevant evidence for this intervention. It was therefore determined that the iSupport programme would not be included in this report. The iSupport programme could be revisited for appraisal after the completion of ongoing studies (Bangor University 2021). The final selection criteria are outlined in Appendix 2.

After the search was conducted, it was clear that there was primary evidence on the START programme available and high number of systematic reviews and meta-analyses on the type of intervention that START represents (e.g. psychoeducational and cognitive behavioural). In line with the priority of evidence sources outlined in the selection criteria (Appendix 2), observational and non-randomised studies were therefore not considered for inclusion. We included primary evidence relating to START and all systematic reviews were assessed to determine which were the most recent and comprehensive, or included particular outcomes of interest not reported elsewhere, and reported outcomes for CBT and psychoeducation separately from other types of intervention. The highest priority evidence from these reviews was then included to provide supporting information on the outcomes of interventions like START. Appendix 4 summarises the selection of articles for inclusion in the review. A single reviewer screened studies and extracted data from relevant sources. A formal quality assessment was not conducted but the strengths and weaknesses of evidence are considered throughout.

Appendix 1. Initial inclusion and exclusion criteria for evidence included in the review

	Inclusion criteria	Exclusion criteria
Population	Unpaid informal carers of people with dementia	Unpaid informal carers of people living in residential care settings Professional carers of people with dementia Unpaid informal carers of people with other health conditions
Intervention	Psychological interventions using cognitive behavioural therapy or psychoeducational approaches	Psychological interventions using other approaches (e.g. peer support, counselling) Multi-component interventions Dyadic interventions
Comparison/ Comparators	Any comparator	-
Outcome measures	Clinical and patient-reported outcomes for both carer and recipient of care Healthcare utilisation and economic outcomes for both carer and recipient of care	
Study design	<p>The following study types were prioritised, in the order listed:</p> <ul style="list-style-type: none"> - Systematic reviews - Randomised controlled trials - Non-randomised controlled trials - Single-arm trials <p>We will only include evidence for “lower priority” evidence where outcomes for each condition/symptom of interest are not reported by a “higher priority” source or where “lower priority” evidence relates to an intervention assessed to be of high potential.</p> <p>We will also search for economic evaluations or original research that can form the basis of an assessment of costs/cost comparison and for qualitative studies that provide information on patient or organisational issues.</p>	
Search limits	None	
Other factors	The topic proposer and assessment group have highlighted Strategies for Caregivers (START) and WHO iSupport For Dementia as high potential interventions and relevant information from randomised controlled trials on these interventions will be included even where “higher priority” sources are available.	

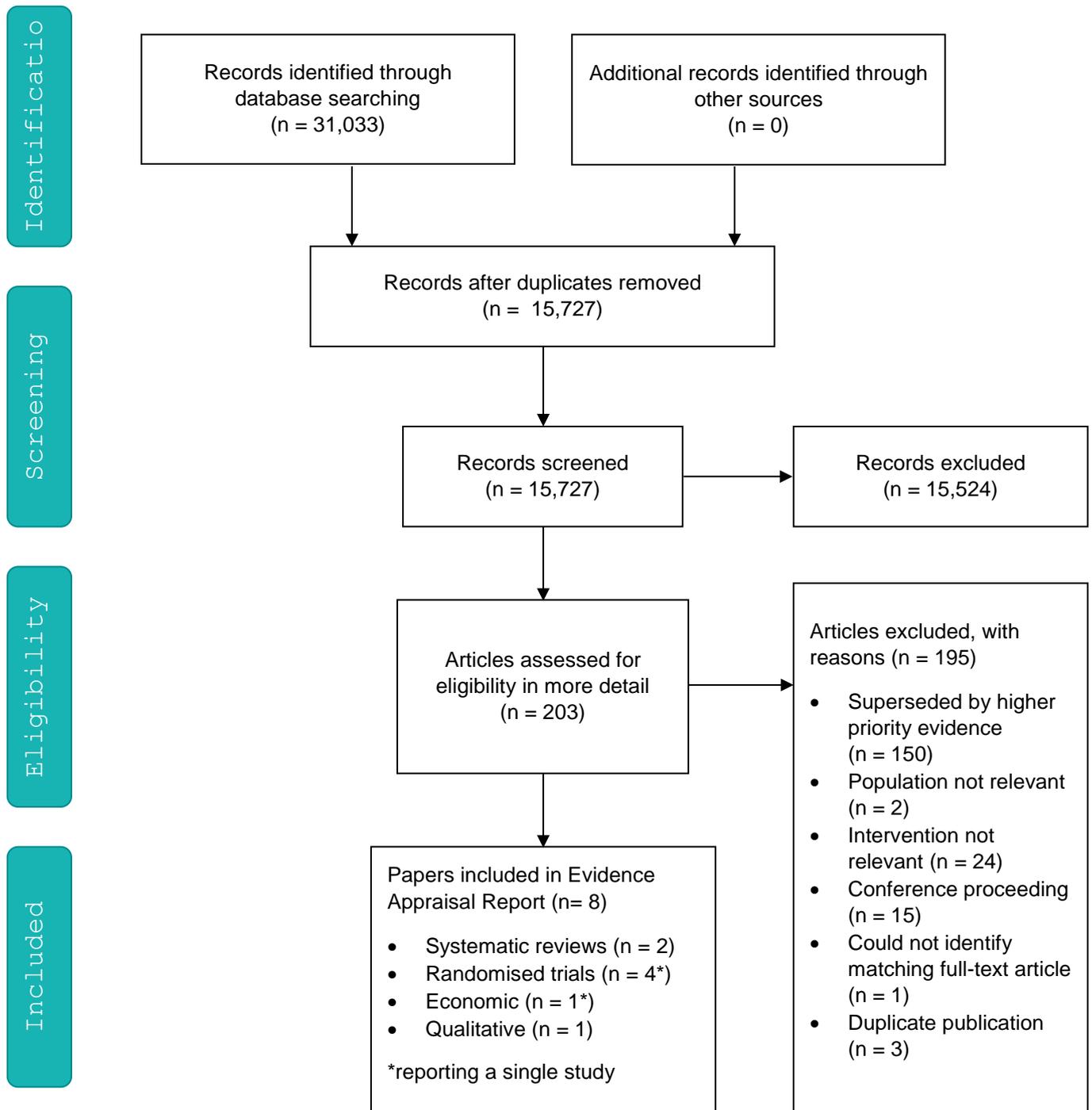
Appendix 2. Final inclusion and exclusion criteria for evidence included in the review

	Inclusion criteria	Exclusion criteria
Population	Unpaid informal carers of people with dementia	Unpaid informal carers of people living in residential care settings Professional carers of people with dementia Unpaid informal carers of people with other health conditions
Intervention	Strategies for Relatives (START) programme	Psychological interventions using other approaches (e.g. peer support, counselling) Multi-component interventions Dyadic interventions
Comparison/ Comparators	Any comparator	-
Outcome measures	Clinical and patient-reported outcomes for both carer and recipient of care Healthcare utilisation and economic outcomes for both carer and recipient of care	
Study design	<p>The following study types were prioritised, in the order listed:</p> <ul style="list-style-type: none"> - Systematic reviews - Randomised controlled trials - Non-randomised controlled trials - Single-arm trials <p>We will only include evidence for “lower priority” evidence where outcomes for each condition/symptom of interest are not reported by a “higher priority” source or where “lower priority” evidence relates to an intervention assessed to be of high potential.</p> <p>We will also search for economic evaluations or original research that can form the basis of an assessment of costs/cost comparison and for qualitative studies that provide information on patient or organisational issues.</p>	
Search limits	None	
Other factors	The topic proposer and assessment group have highlighted Strategies for Caregivers (START) as the highest potential intervention. Secondary evidence for other psychoeducational and cognitive behavioural therapies will be included to provide support for this type of intervention beyond the available primary studies	

Appendix 3. MEDLINE search strategy

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily <1946 to March 22, 2021>	
Caregivers	
1	Caregivers/
2	(carer* or caregiver* or care giver* or caregiving or care giving).tw,kw,kf.
3	1 or 2
Dementia	
4	exp Dementia/
5	(dementia* or Alzheimer* or Alzeimer*).tw,kw,kf.
6	4 or 5
Mental Health & Psychological Interventions	
7	Mental Health/
8	((mental or psychological) adj1 (health or wellbeing or well-being)).tw,kw,kf.
9	exp Mental Health Services/
10	exp psychotherapy/
11	(counselling or counseling).tw,kw,kf.
12	(psychotherap* or psycho-therap* or psychologic* therap* or psycho-logic* therap*).tw,kw,kf.
13	((cognitive behaviour* or cognitive behavior* or behaviour* or behavior* or emotion-focus* or emotion focus*) adj1 (therap* or treatment* or technique*)) or CBT).tw,kw,kf.
14	anxiety management.tw,kw,kf.
15	((coping or psychological or psycho-logical or psychosocial or psycho-social) adj1 (strateg* or intervention* or behaviour* or behavior* or mechanism* or technique* or process* or factor*)).tw,kw,kf.
16	(mindfulness or relaxation or self-help* or selfhelp*).tw,kw,kf.
17	(logotherap* or logo-therap* or narrative therap* or schema therap* or socioenvironment* therap* or socio-environment* therap*).tw,kw,kf.
18	(psychoeducation* or psycho-education*).tw,kw,kf.
19	Health Education/
20	Patient Education as Topic/
21	((health or patient or carer* or caregiver* or care giver*) adj8 education*).tw,kw,kf.
22	Internet-Based Intervention/
23	Internet/
24	((web or webbased or internet or computer or online or on-line or video or telehealth or tele-health or telemedicine or tele-medicine) adj3 (intervention* or therap* or train* or treatment*)).tw,kf,kw.
25	or/7-24
Caregiver and Dementia & Psychological Interventions	
26	3 and 6 and 25
Caregiver & Psychological Burden	
27	Caregiver Burden/
28	27 and 6
29	((mental or psychological) adj1 (exhaust* or burden* or burnout* or burn out* or strain* or stress*)).tw,kw,kf.
30	((carer* or caregiver* or care giver*) adj5 (exhaust* or burden* or burnout* or burn out* or strain* or stress*)).tw,kw,kf.
31	(29 or 30) and 6 and 25
32	28 or 31
Specific programmes/trials	
33	("strategies for relatives" or isupport or famtechcare or "REACH II").tw,kw,kf.
34	33 and 6
Set Combination	
35	26 or 32 or 34
36	limit 35 to english language

Appendix 4. PRISMA flow diagram outlining selection of papers



Appendix 5. Alzheimer's Society Carer Testimonies

Two written testimonials were received to supplement the findings of the focus groups. These are presented verbatim, with no alterations, below.

Testimonial one

Q1. How do your family and friends meet your needs, eg your mental well-being or things you cannot do for yourself.

Not applicable to my circumstances – I am mentally alert (and physically quite fit for my age) but in a way that is absolutely governed by set routines – everything has to be in the right place at the right time! For instance, I am quite pedantic about how I leave the kitchen ready for next morning – no washing-up left, tea making paraphernalia all in place, reminder note to get the butter out of the fridge etc etc!, checking the doors are locked, fridge/freezer doors are closed properly.

Q2. What impact do you think this has on family and friends?

Drives my wife to distraction – but the saving grace there is that she is not very mobile so I am largely left to my own devices. Still my sweetheart, but the poor girl is crippled with a sciatic nerve damaged during a cancer operation - so I am responsible for cooking, cleaning/tidying, shopping, laundry (washing and ironing) and general maintenance. I don't much like gardening! We employ a cleaner once a week so we have a good bottoming of the essential areas. I also have a fortnightly delivery of staple foods but can trot up the hill (Co-Op, 5 mins) for anything we run out of or for fresh fruit and veg.

As to friends and neighbours, because I have explained my condition I get nothing but full and most importantly proactive support from them.

We have a daughter living locally – but poor girl managed to develop COPD to an alarming level (smoking as a teenager and so on) so we don't see her to much as she is in strict self-motivated lockdown. Rest of the immediate family spread around the world – London, York, Cyprus, USA.

Q3. How necessary is it for you to have family and friends to do this, rather than rely on paid-for services?

It's an important and essential part of living with dementia – very comforting to know that IF we need help I have only to ask my neighbours. I trot down to the Post Office/Bank on rare occasions (lockdown rules!) but I know that Margaret is safe. Of course, we are in constant contact with all the family via Skype, Viber, Zoom etc etc.

From the above, I have developed an argument in my mind as to what is the one most single fact that is important to those living with the Alzheimer's condition and it boils down to the fact that anyone living with Alzheimer's needs simple communication with the world outside of themselves. (I have a brother-in-law who has severe memory impairment and to be brutal when you look into his eyes very often there is no one at home. Scary.)

I'm not advocating full blown internet access – just enough capacity to be able to talk to and see family and friends. There are so many devices on the market and not being au fait to any depth I hesitate to recommend one. Certainly nothing as sophisticated as this laptop – something very basic and more in the order of a phone with a big screen which trots round with you in your pocket/handbag. Dug out our old Kindle to see if I can get that to work!

If a device is decided upon it might be worth approaching a large supplier (like Amazon) to see if there might be a discount for those who can produce the magic certificate issued by the doctor! Mine certificate's worth quite a lot in a 25% rate rebate.

Testimonial two

When I was in my caring role I cared for my mother who had mixed dementia. When in a caring role I went through many issues and emotions. A major one for me was crowded isolation. My take on this is that you tend to feel on the outside looking in, also you feel detached from everybody. When caring it is a 24hr job. Appointments ,medication, social services etc. You can get so involved with trying to keep up you feel your the only person in the world having to cope with this.

Every issue or problem can seem a lot bigger than what they are because you're probably trying to deal with too much at once.

I look back to my caring days and think what could I have done better, well I know I could have got support a lot earlier than what I did. That is not to say I was not a good enough carer because I know I was but the point is I was offered support in tools to make my caring better to manage in access to support groups and social activities and my own wellbeing all which points you to a position to know you're not alone and there are good people waiting to help. I found my crowded isolation held me back on so many levels, when you fall into this it is difficult to move forward with your responsibilities and that pressure can affect your own wellbeing which is important for you as well as the person being cared for. Being a carer is a fantastic thing to do for anyone and it's difficult at times but you have to look after yourself to be the best you can be. There are carers all over the world that experience the same as you. I didn't have to feel I was the only one looking in and that's the same for everybody and the reason for this is there are many good organisations that can help. That is not to take over but to support you in your caring role. I reached out to a group called Tide that is This Day In Dementia Everyday. They have supported me in many ways in caring and continue to do so. I am able to take an active role in carer groups, Focus groups and training sessions. You will be meeting other carers who will know how you feel as they have done so. To share your experience can help so much and its such a positive to get out of it. Tide will also give you that chance to give you a voice to put your point forward. All of this support has benefited me so much, even giving me encouragement to carry on with my writing which I let slip but now I'm on a course for creative writing. Tide continue to support many carers all over the united kingdom, there work is crucial to the support and wellbeing of carers to them as a person and to there caring role. This is an account of my caring role yours may be different but if you do identify with my account and get something from it please look for that support. All carers do a valuable service. You matter, and you count. Please feel supported.