Institution: University College London

Unit of Assessment: 10 - Mathematical Sciences

Title of case study: START (STrAtegies for RelaTives) programme: reducing depression and anxiety in family carers of people with dementia at reduced costs

Period when the underpinning research was undertaken:

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Dr Julie Barber	Associate Professor of Medical Statistics	2000 onwards
Dr Aidan O'Keeffe	Associate Professor of Medical Statistics	2013 onwards

Period when the claimed impact occurred: 2014 – 2020

Is this case study continued from a case study submitted in 2014? No

1. Summary of the impact (indicative maximum 100 words)

The START (STrAtegies for RelaTives) intervention is a psychological therapy to reduce anxiety and depression in family carers of people with dementia. It was developed and evaluated by a multidisciplinary team at UCL, including essential contributions from statisticians led by Dr Barber. Statistical modelling showed the START intervention to be cost-effective and clinically relevant over the short- and long-term. The intervention has improved UK policy and guidance on dementia care. The intervention is used in the UK by at least 24 services across 12 NHS Trusts and by charities such as the UK Alzheimer's Society. It has also been translated and adapted for use in 5 other countries: Australia, Spain, Japan, India and Hong Kong.

2. Underpinning research (indicative maximum 500 words)

The increasing dependence and challenging behaviour of people with dementia strongly affects the mental health of family members, who provide much of their care. Approximately 40% of these carers have clinical depression or anxiety, while others have significant psychological symptoms. Evidence from systematic reviews suggests that psychological interventions individualised to the carer are most effective in preventing breakdown of patient care and delaying care-home admission. As the number of people with dementia in the UK is projected to increase by 80%, from almost 885,000 in 2019 to around 1,600,000 by 2040, it is critical to develop strategies to decrease the distress of carers.

Dr Julie Barber (UCL Statistical Science), together with a multi-disciplinary group of researchers led by Professor Gill Livingston (Division of Psychiatry, UCL), developed and evaluated the STrAtegies for RelaTives (START) intervention; a programme of therapy and coping strategies for dementia carers. The multi-disciplinary team comprised clinical psychiatrists specialising in older adults, clinical psychologists, neurologists, qualitative researchers, health economists, and statisticians. Dr Barber led the statistical team and was responsible for all statistical aspects of the evaluation of the START intervention.

In 2009, the research team conducted a randomised trial of START. The trial recruited 260 carers, who were randomly allocated to the intervention (START) group and to the 'treatment as usual' (TAU) control group in a 2:1 ratio. Within the intervention group, participants received 8 sessions of manual-based therapy (performed according to specific guidelines to maximise consistency), delivered over 8-14 weeks by psychology graduates supervised by the research team. This was the first UK randomised trial on the clinical effectiveness (long-term reduction of depression and anxiety symptoms) and cost effectiveness of individual manual-based therapy for dementia carers.

Dr Barber's research is predominately in design and analysis of randomised trials of new health care interventions. She led all statistical aspects of the START trial, including

inputting into the design of the trial; designing the statistical analyses, including identifying and evaluating optimal methods; supervising the data preparation and analysis; and writing peer-reviewed articles. The effect of the START intervention was evaluated after 4 and 8 months (**R1, R2**), 24 months (**R3**), and 6 years (**R4**). Dr Barber supervised two statisticians, Mark Griffin (UCL Primary Care and Population Health) and Dr Aidan O'Keeffe (UCL Statistical Science) in analysis of the clinical data and advised the Health Economists on statistical analysis of economic outcomes (**R2, R3, R4**).

Dr Barber's underpinning research in design and analysis of trials allowed her to ensure the most appropriate and up-to-date methods were used for the START evaluation. Her analysis plans incorporated new statistical methodologies which had not previously been widely used in applied research, but which were essential to address specific complexities of the START trial design, ensuring unbiased and precise estimates of the intervention effect. In particular, she identified that modelling needed to account for the clustering of outcomes for carers receiving the intervention from the same therapists. Typically in previous trials, such clustering had been ignored, but Dr Barber's research identified that this approach could result in inflation of type 1 errors and in false claims of important intervention effects. The START analysis was therefore carried out using a particular specification for a multilevel mixed-effects model that allowed for differential clustering in the trial arms (**R1, R2**). For the 6-year evaluation, Dr Barber found that results from analyses of the longitudinal HADS-T scores could be biased due to "informative censoring" when the person with dementia was admitted to a care-home or died. Informative censoring is usually ignored in trial analyses, resulting in estimation of potentially incorrect intervention effects. To address this Dr Barber used joint mixed effects models that incorporated time until institutionalisation or death alongside the HADS-T measurements (**R4**).

Analysis of HADS-T over the 8-month evaluation period showed a significant improvement in anxiety and depression for carers receiving the START intervention. For the depression sub-score, carers who participated in the TAU group were four times more likely to have clinically significant depression compared with those who received START (**R1**). The corresponding economic calculations demonstrated a high probability of cost effectiveness (**R2**).

The positive clinical effect of the START intervention was sustained after 24 months, as evidenced by improved carer mood and lower anxiety levels (lower HADS-T) (**R3**). START was also shown to be cost effective with respect to carer and patient outcomes, and National Institute for Health and Care Excellence (NICE) thresholds.

The most recent analysis over a 6-year period, showed that carers who participated in the START programme were five times less likely to have clinically significant depression than carers in the TAU group (**R4**). Costs of care were nearly three times lower among families in the START group (GBP5,759 per patient) compared with the TAU group (GBP16,964 per patient), likely due to the improvement in family carers' mental health and quality of life (**R4**).

3. References to the research (indicative maximum of six references)

R1. Livingston G, **Barber J**, Rapaport P, Knapp M, Griffin M, King D, Livingston D, Mummery C, Walker Z, Hoe J, Sampson E, Cooper C. (2013). Clinical effectiveness of a manual based coping strategy programme (START, STrAtegies for RelaTives) in promoting the mental health of carers of family members with dementia: pragmatic randomised controlled trial. *BMJ*; 347: f6276. doi: 10.1136/bmj.f6276

R2. Knapp M, King D, Romeo R, Schehl B, **Barber J**, Griffin M, Rapaport P, Livingston D, Mummery C, Walker Z, Hoe J, Sampson E, Cooper C, Livingston G. (2013). Cost effectiveness of a manual based coping strategy programme in promoting the mental health of family carers of people with dementia (the START (STrAtegies for RelaTives) study): a pragmatic randomised controlled trial. *BMJ*; 347: f6342. doi:10.1136/bmj.f6342

R3. Livingston G, **Barber J**, Rapaport P, Knapp M, Griffin M, King D, Romeo R, Livingston D, Mummery C, Walker Z, Hoe J, Cooper C. (2014). Long-term clinical and cost-effectiveness of psychological intervention for family carers of people with dementia: a single-blind, randomised, controlled trial. *Lancet Psychiatry*; 1(7):539-548. doi: 10.1016/S2215-0366(14)00073-X
R4. Livingston G, Manela M, Rapaport P, Cooper C, O'Keeffe A, Knapp M, King D, Romeo R, Mummery C, Walker Z, Hoe J, **Barber J**. (2020.) Clinical effectiveness of START (STrAtegies for RelaTives) psychological intervention for family carers and the effects on cost of care for people with dementia: six year follow-up of a randomised controlled trial. *British Journal of Psychiatry*; 216(1):35-42. doi: 10.1192/bjp.2019.160

4. Details of the impact (indicative maximum 750 words)

The number of people living with dementia is rising rapidly owing to increased longevity. Two-thirds of people with dementia (approximately 567,000 in the UK) live at home, with their family providing most of their care (**S1**). According to the Alzheimer Society's estimation, more than 600,000 family members provide GBP13,900,000,000 per year of unpaid dementia care in the UK, however, 40% of the family carers have a clinical depression or anxiety, while others have substantial psychological symptoms (**S1**). Family care is pivotal as it exerts a 20-fold protective effect against the risk of care home admission (**S1**). Therefore, the wellbeing of family caregivers and providing them with effective support is crucial.

The usefulness of the START psychological intervention for family carers was evaluated in a well-conducted randomised trial, which relied on use of optimal statistical methodologies to ensure accurate and unbiased estimates of the intervention effect. This trial provided robust evidence of clinical and cost-effectiveness of the intervention and has subsequently influenced decisions about guidelines, policy and practice for supporting family caregivers.

Approximately 66% of trial participants continued to use the techniques they had been taught after the programme ended (**S2**). The manual and associated resources to deliver the intervention are freely available and can be downloaded (in English, Urdu, Spanish and Japanese) from the UCL website (**S3**). The page has been viewed approximately 30,000 times until the end of 2020 (**S4**).

Changes to UK guidelines and policy on improving dementia care

The evidence of START's effectiveness has led policy makers to cite it in national guidance and policy documents. The UK Government included START **in The Prime Minister's Challenge on Dementia 2020** (published in 2015), which set actions to improve dementia care, support and research in England (**S5**). They noted that "Carers of people with dementia undoubtedly provide a vital role and we know that the availability of appropriate care and support and the quality of services has a significant bearing on whether carers feel able to take a break from their caring responsibilities" (**S5**). The government recommended carers of people with dementia should be aware of and be offered the opportunity for respite, education, training, emotional and psychological support, to better enable them to cope with their caring responsibilities. To allow carers to have a life alongside caring, the guidelines recommend that more employers should have carer friendly policies and practice enabling more carers to continue working and caring. The Government also mandated that NHS England (2016-2017) should provide measurable improvements in all areas of the policy, including quality of post-diagnosis treatment and support for people with dementia and their carers (**S5**).

The Chief Executive of **Alzheimer's Research UK** (the country's leading dementia research charity) acknowledged the programme's importance: "Around 23,000,000 people in the UK – roughly a third of the population – have a close friend or family member with dementia, and it's these unsung heroes who take on much of the strain of the condition. It's important to find ways to support carers and protect their health, and these results suggest that the START programme can help reduce anxiety and depression for carers" (**S6**).

START was evaluated in the **National Institute of Clinical Excellence (NICE) guidelines on Dementia** (NG97 Assessment, management and support for people living with dementia and their carers; June 2018). The NG97 evidence committee noted, "The evidence from the 2014 Livingston HTA report which demonstrated that successful non-pharmacological interventions for managing non-cognitive symptoms could be cost saving, due to the reductions in subsequent treatment costs for those receiving early interventions. The committee agreed that this recent HTA report represented the best quality economic evidence available and supported the recommendation for the first line use of non-pharmacological management" (**S7**). Whilst the document recommended a variety of approaches for carer support, such as START or a similar intervention, the committee agreed that "the topics covered by START are a good representation of the topics that should be covered in this type of intervention" for carers (**S7**).

Improving mental health of dementia patients' carers and support workers

The publication of the START intervention has generated a lot of interest and enthusiasm from NHS trusts for its adoption and it is now being delivered in one third of London memory clinics.

The Alzheimer's Society (the UK's leading dementia support charity) provided funding for dissemination of START, allowing training of 134 clinical psychologists and 39 admiral nurses in 9 UK locations from October 2014 to September 2015. Since then, the UCL team has provided training for 30 staff members in another London trust (NELFT) and others are being trained by the members of the dissemination groups. These trained professionals then cascaded training to others in their area, and this resulted in START being delivered locally to 136 carers across 11 service areas in 2016. A survey carried out in July 2018 by the UCL team indicated that **START is being used by at least 24 services over 12 NHS trusts, with approximately 192 carers** having received the intervention in 2017 (**S8**)**.** Individuals who completed the training reported better understanding of the condition and how it can cause challenging behaviour. This understanding made it easier for them to cope with psychological distress and improved their wellbeing, with a related improvement in their ability to provide care: "Yesterday I had the feeling of happiness I haven't had in a long time. I suddenly felt positive and 'able" (**S8**). This is echoed by voices from the dementia support workers, START facilitators and managers at the Alzheimer's Society:

"The work I got to do with START was really meaningful. Personally, I feel that START gave me the opportunity to work closely with carers, building a relationship that I normally wouldn't get to, helping them to deal with the everyday practical sides of caring";

"I really enjoyed making an actual difference to people's lives, literally (…) the feedback from the carers is that it does work (…) it's nice to know that there is a tool that can help carers that are really struggling";

"That day is hard, seeing the consultant, trying to get ready and it's a heavy day. Whereas with this, it's in someone's comfortable space and it's at their own time and it's looking at strategies (…) The things that maybe aren't discussed with GPs or even a support worker on a home visit. This really opens up quite a lot more, it helps with exploring a lot more detail into what's happening in the home and I think that's really good";

"I felt like it really highlighted and made my job more meaningful, because often I would come away thinking I've not done anything other than sat with a family for an hour and a half and talked about what dementia is (…) START actually gave them that one to one, especially for the carer [to] actually help the person with dementia in the long run" (**S8**).

Worldwide implementation of the START intervention

The START intervention has also been adopted by the international community. An online video conferencing version of START was developed in **Australia** to enable delivery of the intervention from Melbourne and Perth to people in remote communities**.** By November 2018**,** 4 therapists had completed extensive training provided by UCL researchers and 28 carers had already completed the 8-week programme (**S9**). Work in 2018-20 enabled delivery to the **South Asian community** (Urdu translation)**.** Translation of the START

manual into Japanese (2019) enabled 14 people to receive the intervention in an ongoing study in **Japan**, with 27 receiving training by February 2020 (**S9**). A START pilot project was conducted in **Hong Kong,** where 13 family carers have received training since the manual was translated into Chinese in 2017. Translations into Tamil and Hindi have been trialled successfully and START is now being delivered remotely in **India** (Chennai, Mysore and New Dehli) (**S10**)**.** In **Spain** it was trialled in 4 people after consultation about the translation. Unfortunately, plans for the regional authorities to begin implementation in Northern Spain have been delayed by the COVID pandemic (**S10**).

START has been adapted (in collaboration with UCL) for delivery in several different contexts and populations. The UCL Institute of Neurology adapted and trialled START for patients with **Parkinson's Disease dementia**, and it has been adapted to **Lewy Body Dementia** (with training already delivered to carers through third sector partners). Furthermore, the success of the START intervention built a team and a method that led to funding further research programmes focused on dementia. These include the DREAMS-START intervention involving a similar style of intervention to improve sleep in people with dementia living at home and a project to improve quality of life in people with dementia.

5. Sources to corroborate the impact (indicative maximum of 10 references)

S1. Report "Dementia – the true cost: Fixing the care crisis" (May 2018) and article Dementia Tax article published on Alzheimer's Society website corroborate the importance of care provided by family members to dementia patients. Article "Predictors of institutionalisation in people with dementia" published in Journal of Neurology, Neurosurgery and Psychiatry (2003) corroborates the number of dementia patients and cost of care
S2. Evaluation of START intervention published in BMJ Open corroborates the continued use of the intervention after the end of the therapy.
S3. START resources website corroborates availability of START training in different languages.
S4. Supporting correspondence with numbers of START resources' website visits corroborates number provided.
S5. Policy Paper "Prime Ministers Challenge on Dementia 2020" (21/02/2015) corroborates statement provided, government's recommendations to improve dementia care and support for family carers.
S6. News post on Alzheimer's Research UK website (16/07/2014) corroborates Chief's Executive statement on START programme.
S7. National Institute for Health and Care Excellence guidelines on Dementia (page 347) (June 2018) corroborates recommendation of START programme for the first line use of non-pharmacological management for managing non-cognitive symptoms in carers.
S8. Results of the survey on training and implementation of START conducted by UCL Division of Psychiatry (July 2018) corroborates numbers of trainings, trained carers and the intervention implementation; Supporting statements from carers and Dementia Support Workers/START facilitators, and Managers at the Alzheimer's Society corroborate statements provided.
S9. Article (23/04/2020) published in Dementia journal corroborates adaptation of the START program in Japan; Project summary "Strategies for relatives (START) Online" (November 2018) corroborates adaptation of the START program in Australia.
S10. Supporting statements from Clinical Psychologist (01/04/2019) and Clinical Neurophysiologist (09/03/2020) corroborate adaptation of the START program in Hong Kong and Spain; Interview with Consultant Psychiatrist (11/12/2019) published on Reddif website corroborates adaptation of the START program in India.