

The EAST-Dem study: a pilot cluster randomised controlled trial

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Abstract

We recruited 8 GP practices for a pilot cluster randomised controlled trial (RCT) of a DVD/leaflet encouraging South Asian people to seek timely help for memory problems. Primary outcomes were feasibility (proportion of patients expressing interest, consenting) and acceptability. Seventy-eight of one hundred and two (76%) potential participants consented; 76/78 (97%) were followed-up. Thirty-seven of forty-one (90%) receiving the intervention rated this acceptable. Only 17/41 (41%) accessed it; they appeared then to be more likely to seek timely help. The intervention was acceptable and feasible but a full scale RCT would be very expensive. It may be proportionate to make this intervention available without a full-scale RCT.

This trial is listed on the ISRCTN registry with study ID **ISRCTN67269658**.

Key words: cross-cultural; dementia; diagnosis and classification; education

Source of funding: NM is funded by the NIHR, grant number DRF-2012-05-141.

The views expressed in this paper do not necessarily reflect those of the NIHR, the Department of Health or the NHS.

Introduction

It is estimated there are 850,000 people living with dementia in the UK, and the number of people affected is expected to increase to over one million by 2025 (Prince *et al.* 2015). Obtaining a diagnosis of dementia early in the illness means that psychological and pharmacological treatment can start earlier. This has the potential to improve cognitive function and carers' mental health at an earlier stage. In the UK, minority ethnic people account for 15% of the English population and 39% of the London population (Office for National Statistics, 2007) and around 7% of the population is of South Asian origin, meaning they have links with countries in Southern Asia such as India, Pakistan and Bangladesh.

People from minority ethnic groups with dementia are less likely to receive a timely diagnosis and more likely to be diagnosed when presenting in a crisis compared to the White British population (Mukadam *et al.* 2011b). They also have lower scores on cognitive testing at initial memory services presentation indicating help-seeking at a later stage of dementia (Tuerk and Sauer, 2015).

We have previously reported on the development of a trilingual DVD and bilingual leaflet intervention emphasising that dementia is a physical illness and the benefits of early help-seeking for memory problems in South Asians (Mukadam *et al.* 2015; Mukadam *et al.* 2011a), alongside development and validation of the Attitudes of People from Ethnic Minorities to help-seeking for Dementia (APEND) questionnaire (Hailstone *et al.* 2016). The APEND questionnaire is composed of 19 items scored on a Likert scale and measures intention to carry out a behaviour (behavioural

intention) as well as influences such as societal norms that impact on behavioural intention. Behavioural intention is scored out of nine, with a higher score indicating a greater intention to seek help for memory problems.

Using these tools, we aimed to:

1. Test the feasibility of a full trial of our intervention. Feasibility was pre-specified as:
 - a. $\geq 70\%$ of participants who expressed an interest in participating would consent.
 - b. $\geq 80\%$ of participants who enrolled initially would participate in follow-up.
2. Test acceptability of the intervention.

We also explored the intervention's impact on participants' attitudes to help-seeking for memory problems (behavioural intention on the APEND questionnaire), hypothesising that the intervention would result in increased intention to seek help for memory problems in those who received it.

Methods

We obtained approval from the National Research Ethics Service (NRES) committee Fulham and registered the trial on the ISRCTN registry with study ID ISRCTN67269658. We recruited Greater London primary care (GP) practices and randomised in clusters (at level of GP practice) to prevent intra-practice contamination. A researcher independent from the study randomised blocks of two or four practices using a random number generator. South Asian patients over the age of 50 without a recorded dementia diagnosis, living at home were eligible for participation. This age group was chosen based on feedback from participants in an

earlier study (Mukadam *et al.* 2015) who suggested this age group would be likely to know people with cognitive problems and dementia. All eligible patients in participating practices were initially sent a letter in English asking them to contact NM if they were interested in participating in a research project, and offering a voucher for their time. This letter did not specify that the research project was about memory problems or dementia.

The intervention (leaflet and DVD) was sent to consenting participants registered to GP practices in the intervention arm with a letter on headed paper from the practice. We chose this method of dissemination for the intervention as previous literature suggests that people pay attention to letters received from their primary care physicians and that this increases engagement in studies (Hewitson *et al.* 2011). Participants from control GP practices received treatment as usual.

NM (who was not blind to randomisation status) assessed participants in person after receipt of the intervention (T1) and then participants completed a follow-up questionnaire three months after the initial visit (T2), either face-to-face or via email/post depending on personal preference. The questionnaires were written in English but translated as needed for individuals. At T1, participants filled in a consent form and self-completed a questionnaire consisting of demographic information, information about experiences of dementia (family caring and professional), and the APEND questionnaire. They rated intervention acceptability on a 5-point Likert scale, from completely unacceptable to completely acceptable.

Analysis

We calculated percentages of people who consented to take part, who completed follow-ups and who rated the intervention as either “somewhat” or “completely acceptable” on the scale.

We used linear mixed models analysis (Laird and Ware, 1982) with intention to seek help, as measured on the APEND questionnaire, as the main outcome, including data from both time points in analyses. Intention to carry out a behaviour strongly predicts actual behaviour (Ajzen, 1991). Linear mixed models is relatively robust to violations of assumptions about data, particularly where the number of participants is greater than 50 (Jacqmin-Gadda *et al.* 2007).

Results

Figure 1 shows the CONSORT flow diagram of recruitment.

Participants in the intervention and control groups were similar in age (64.5 vs 63.6) but the intervention group had a greater proportion of male participants (56 vs 43%), had on average three years less of education and more frequently needed an interpreter (34 vs 11%). Most of the control group participants were registered to GPs in inner London (n=30, 81%) whereas most of the intervention group were from greater London (n=38, 93%). Participants in the intervention and control groups had similar experiences of caring for or working with people who had dementia or memory problems.

1. Feasibility of recruitment.

Seventy-eight out of one hundred and two (76%, 95% Confidence Interval 67 to 84%) people who expressed an interest in the study, consented to take part in the

study and completed an initial questionnaire. 41 were allocated to the intervention and 37 to the control arm.

2. Acceptability of receiving study materials.

Thirty-seven out of forty-one (90%, 95% Confidence Interval 77 to 96%) participants in the intervention group rated acceptability of the items they received as either “somewhat acceptable” (6/37) or “completely acceptable” (31/37; 83.8%), 1 rated the items as “neither acceptable nor unacceptable” and 3 other participants did not answer this question. There were no complaints or expressions of distress at receiving any of the study materials.

3. Rates of follow-up.

Seventy-six out of seventy-eight (97%, 95% Confidence Interval 91 to 99%) completed the follow-up questionnaires.

Seventeen out of forty-one people (41%) said they had accessed the intervention. Ten looked only at the leaflet, three only looked at the DVD and four people looked at both leaflet and DVD. Twenty-three had not and one did not answer.

Linear mixed models with a fixed effect for time and the intervention and a random effect for subject, adjusted for sex, age and education showed that behavioural Intention scores did not differ significantly between intervention and control groups over time (Parameter estimate -0.5, 95% CI -2.2 to 1.2, $p=0.56$). None of the other subscales differed significantly between groups.

As an intervention cannot have an effect unless it is engaged with in some way, we compared in a post-hoc analysis, scores on Behavioural Intention between control

group and intervention group participants who reported that they had viewed the intervention. We used the Mann Whitney U test as the subscale scores were not normally distributed. In this sub-group, the mean difference on the Intention subscale was significantly higher (intervention group 1.5 points higher; $U= 212.5$, $Z= -2.1$, $p=0.037$).

In order to explore whether this finding could be due to demographic confounders we compared those who said they viewed the intervention with the control group and found no significant differences between the two groups on age, gender, years of education, occupational classification, number of years in the UK or experience of dementia.

Discussion

This study is the first to design and test an intervention to encourage help-seeking for dementia earlier in the South Asian population and as such is likely to represent the best level of evidence in this under-researched and hard to access population. All pre-stated criteria for feasibility, acceptability of intervention and follow-up rates were met. The study was not powered for efficacy, as we had no information on numbers needed. We did not find any differences in intention to seek help for memory problems on the APEND questionnaire subscales. The data suggested that people from the control group were more likely to view help-seeking more favourably and we judge that this was likely explained by higher levels of education in the control group. However there was an increase in score on the intention subscale of the APEND in those who viewed the intervention compared to the control group. These results have to be viewed with caution as they were an unplanned analysis and the chances of a spurious result increase with the number of statistical analyses.

However, the findings were not explained by measured confounders and make logical sense as we cannot expect to influence attitudes with any intervention unless people engage with the intervention in some way. As less than 50% of participants viewed the intervention, our method of posting the intervention was not adequate and it may be that engagement with the intervention could be improved, for example, by marking posted materials with the National Health Service symbol or sending postal reminders to participants. The intervention may also be better disseminated through, for example, community centres or placement in primary care practices.

Limitations of the study include that although we chose practices with high South Asian populations and contacted 1459 people, initial contact letters were only written in English and we recruited only 78 people and 41% of those randomised read the intervention, therefore there is a possible selection bias. However, the difficulty of recruiting in this way from primary care is also an important addition to the literature in this difficult to reach group. As this was a feasibility study, researchers were not blinded to allocation status so there was the risk of observer bias. Participants filled out the questionnaires in a face-to-face interview at T1 which could have led to social acceptability bias.

Given the acceptability of the intervention, the lack of harm and its simplicity and that it may improve attitudes to earlier help-seeking for dementia, it would be proportionate to disseminate it without a full-scale RCT, as the latter is likely to be expensive and impractical.

Conflict of interest

None

Description of authors' roles

All authors designed the study, planned statistical analyses and wrote the paper. N.

Mukadam collected data and carried out statistical analyses.

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Figure 1: CONSORT flow diagram

