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# Evaluating a brief intervention for mealtime difficulty on older adults with dementia

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## Abstract

**Aims and objective:** To test a spaced retrieval intervention using spaced retrieval to alleviate mealtime difficulties in older people with dementia.

**Design:** A single-case study design.

**Setting:** Nursing Homes in North Central England, United Kingdom.

**Participants:** Older people with Alzheimer's disease.

**Methods:** A single-case study using an ABA design was used. Data were collected using the Edinburgh Feeding Evaluation in Dementia scale, Mini Nutritional Assessment, and Body Mass Index before intervention, postintervention and following 3 months of postintervention. Realist evaluation was used to identify for which participants the intervention was effective, and an economic evaluation was also carried out.

**Finding:** Of 15 participants who entered the study, eight completed all phases of the study. A mean 104.4 h were needed to deliver the intervention. The number of sessions required ranged from 90–222. The length of time each participant retained information (for all sessions) ranged from 13–28 min. Participants had most difficulty with: “putting food into mouth and chewing it”; “realizing it was mealtime”; and “eating a whole meal continuously.” A reduction in the difficulty with mealtimes occurred between phase A1–A2 for most participants. Six participants maintained this in phase A3. Similar patterns were evident for nutritional scores. For most participants, the effect size of the intervention was moderate or large.

**Conclusions:** Spaced retrieval is useful in reducing mealtime difficulties in older participants with dementia. While the results of this study are promising, further large and multicentre trials are needed to explore the effectiveness of the intervention in diverse populations.

## KEYWORDS

dementia, mealtimes, nutrition, older people, single-case study, spaced retrieval

## 1 | INTRODUCTION

Increasing age is associated with various health conditions including dementia, a neurological term referring to a chronic and progressive condition characterized by disturbance of multiple higher cortical functions such as memory, cognition, orientation, comprehension, calculation, learning capacity, language and judgement and general difficulties in carrying out activities of daily living (Schoeni et al., 2018; World Health Organization, 2012). Approximately 6%–10% of older people aged 65 are affected by various forms of dementia (Liu et al., 2014). Estimates suggest that the number of people affected by dementia will rise to 65.7 million by 2030 and 115.4 million by 2050. In up to 10% of cases, the onset of dementia is prior to the age of 60 years (Prince et al., 2013; Schoeni et al., 2018), and the prevalence of dementia doubles with every 5-year increment in age. Dementia contributes to significant disability and dependency among older people in developed and developing countries (World Health Organization, 2012).

### 1.1 | Mealtime difficulties and dementia

Dementia is associated with mental, cognitive, physical and psychological impacts on the affected individual. One of the common problems associated with the later stages of dementia is its effect on mealtimes abilities. While changes in mealtime ability in older people with dementia may include undereating or overeating (Cipriani et al., 2016), ultimately older people with dementia have difficulty in moving food from a plate to the mouth and chewing and swallowing it, resulting in reduced food intake and sequelae including undernutrition (Siebens et al., 1986; Watson, 1993).

### 1.2 | Alleviating mealtime difficulty

A recent review of interventions to alleviate mealtime difficulty in older people with dementia (Rehman et al., 2019) highlighted that most studies are affected by various limitations and these include issues with randomization or control groups, small sample size, lack of sample size calculation, power analysis, issues with blinding. The reviews also highlighted the need to use standardized interventions and outcomes to enable comparison and meta-analysis. On the one hand, there must be agreement on which outcomes are most likely to be useful and agreement around what is considered clinically effective and how long interventions should be applied so that positive effects are likely to be observed.

While no clear evidence of effectiveness of any particular intervention was evident, the potential for spaced retrieval and Montessori methods was mentioned in four systematic reviews (Bunn et al., 2016; Herke et al., 2018; Leah, 2016; Liu et al., 2015). Spaced retrieval is one such technique used to enhance prospective memory. The technique involves repeating or practicing information or technique to be learned at set uniform or different and

increasingly spaced time intervals (Haslam et al., 2011). The person undertaking the task is required to repeat a given set of information at a certain time, and each new practice is expected to have a longer period between the previous and the scheduled rehearsal. A test is also taken at each rehearsal/practice time to determine the amount of information retained by the participant. The technique was first investigated by Landauer and Bjork (1978) who used flash cards to help participants to recall information at increasing time intervals. Findings suggested that increasing space between practice or rehearsal result in improved outcomes.

The technique is used and found helpful in improving memory of patients with dementia, as the patients are able to remember names (Hawley et al., 2008), faces (Hawley et al., 2008; Hopper et al., 2010), daily routine, tasks and information about themselves etc. (Small, 2012). Evidence suggests that the approach helps older adults with dementia to maintain their cognitive skills with a high success rate (Small, 2012).

Spaced retrieval has been demonstrated to be effective in alleviating mealtime difficulty in older people with dementia as described by Brush and Camp (1998) as: "...a technique during which retrieval of information is practiced at increasingly longer intervals of time." The efficacy of spaced retrieval at alleviating mealtime difficulty in older people with dementia was first demonstrated by Lin et al. (2010) in a randomized controlled trial (RCT) where it was shown to reduce difficulty, increase the amount of food eaten and to improve body mass index. Husak and Page (2017, p. 6) summarized the evidence from existing studies on the use of spaced retrieval in the alleviation of mealtime difficulty in older people with dementia and concluded that: "Results from these studies showed statistically significant gains and medium to large treatment effects in favor of SR when compared to a control group receiving routine care."

However, despite the demonstrated effectiveness of spaced retrieval methods at alleviating mealtime difficulty in older adults with dementia, the interaction with the participants in the studies reported to date represents a considerable investment in time and effort: up to 8 weeks with 24 interactions in one study (Wu & Lin, 2013). While such interventions seem to be effective, the review of this evidence clearly highlights that the number of studies exploring the effectiveness of spaced retrieval is very small. In addition, these studies are conducted in only one country by two main authors. Therefore, while we have a "proof of concept" regarding the effectiveness of these interventions, we do not know if their effect is sustained and, in terms of cost-benefit if they are feasible in nursing home environments. These interventions are very expensive, labour-intensive, prolonged and may not be applicable widely, and it is necessary to study whether they are sustainable. It is also necessary to investigate what factors: situational (Palese, Decaro, et al., 2020; Palese, Gonella, et al., 2020); environmental (Palese, Gonella, et al., 2020; Palese, Grassetti, Bressan, et al., 2019); and individual (Palese, Grassetti, Zuttion, et al., 2019) that influence the outcome of the intervention. A RCT—while remaining the gold standard method of testing interventions—may not be the best design to achieve this and an alternative approach may be required.

RCTs, in addition to requiring large samples that may be unattainable with this patient group, also require an element of blinding, which would be hard to achieve with an educational intervention. Moreover, there is considerable heterogeneity among older people with dementia and we wished to study what worked for whom in the present study. Towards that end this study was conducted with the following aims and objectives:

- To investigate the use of spaced retrieval, for the alleviation of feeding interventions in older people with dementia using a single-case experimental approach.
- To conduct a realist evaluation of the intervention to explore what works for whom in what circumstances.
- To explore the costs involved in delivering the brief intervention expressed as cost per kilocalorie (kcal).

## 2 | METHODS

This study used a single-case experimental design (SCED) which refers to an experimental method which is used to test the efficacy of an intervention using a small number of participants (James, 2016) and involves repeated measurements, sequentially (sometimes with randomization) introducing an intervention, specific data analysis and statistics. This design is commonly used in the fields of psychology, counselling and education (Stapleton & Hawkins, 2015). Participants serve as their own controls and the design relies on replicating interventions to determine their efficacy across individual subjects and not groups (Miller & Lee, 2013).

The method used in this study resembled the approach by Lin et al. (2010) who used an RCT design to determine the effectiveness of spaced retrieval training methods in reducing mealtime difficulties in older adults with dementia. However, as opposed to using an intervention group and a control group, we used a SCED. The reasons for this are mainly related to the advantages this offers and these relate both to the theoretical framework for the study, and the realist evaluation component of the study. RCTs compare large groups of people but mask how individuals react to the intervention, how long they take to respond and how long that effect lasts. As such, they achieve proof of concept but do not help carers to design individualized person-centred interventions which are at the heart of nursing care. We also consider that the chosen approach for our study was innovative as this is also the first time, SCED design has been used in the context of mealtime difficulties in older adults with dementia. Older adults with dementia are individuals with varied needs, health problems and profiles, and many different issues affect their ability to cooperate with and respond to the intervention. Therefore, SCED explicitly uses individuals as their own controls to measure progress and permits individual factors to be explored. Another innovative aspect of the study was the inclusion of phase A3 to determine the sustainability of the impact of the intervention.

While there is no formal published guidance related to sample size for either single-case studies or realist evaluation, available

studies have often used a sample between 2 and 10 participants (Price et al., 2018). Therefore, single-subject research designs are sometimes called small-*n* designs. The method is very labour-intensive and aimed at a detailed examination of individuals and a search for patterns across individuals; therefore, a sample of 20–25 participants was considered possible in the time frame of the study. It is recommended by Lobo et al. (2017) that, following the baseline phase, a minimum of five data points is collected, and we tried to collect six in the main intervention phase.

### 2.1 | ABA design

We applied an ABA design which comprised:

A1: Baseline data were collected by observing and measuring the dependent variable before the introduction the intervention.

B: The second intervention phase involved administration of the intervention (independent variable) to the participants. Multiple observations or measurements were taken to record the effect of treatment.

A2: In this phase, the intervention was removed.

Following phase A2, we followed up after 3 months to explore the sustainability of the intervention.

### 2.2 | Spaced retrieval intervention

#### 2.2.1 | Screening

The setting for the study was two private nursing homes in the same city. These were selected as they were known to care for older people with dementia and access was arranged through the companies owning the homes. The homes housed 57 and 60 residents, respectively, and catered for a range of care dependency, including people with dementia. Care in these homes is paid for through a means tested fee whereby people contribute financially to their own care and if they cannot afford this a local government contribution is made. Care is provided for largely by care assistants who are not Registered Nurses but have undergone a short programme in personal and social care. On each shift, at least one, and commonly only one, Registered Nurse will be present. Medical services are provided by the residents' own general practitioners.

Following the recruitment of participants, a 40–60-min screening session was arranged which involved exploring whether the participant was able to communicate effectively, pass one item spaced of retrieval screening and a reading test (Brush & Camp, 1998). The first author, using her first name, introduced herself and participants passed if they could state her name correctly after a 1-min interval. To assess the ability to communicate, read and respond, each participant was asked to read some information presented in cue cards; a score of 90% or above of reading accuracy was required to pass the reading test. This score was

calculated by identifying the total number of words read correctly and dividing them by the total number of words. The participants were then asked to follow a simple series of directions such as “tap the table” and “close your eyes.” Participants who passed the screening test first time were included in the study. However, those who did not pass the screening test were retested after at least 2 days of the initial screening session. A maximum of three attempts were made and participants unable to pass the test on all three occasions were excluded from the study. Of 32 participants who were screened, three participants did not pass the screening (one item screening and reading test) and were excluded from the study. Therefore, 29 participants were included in the first phase (A1) of the study.

### 2.2.2 | Intervention

The intervention in this study consisted of 40–60-min sessions three times a week (Monday, Wednesday and Friday) for 8 weeks involving participants in spaced retrieval activities designed to help them re-learn a fixed series of activities related to recognizing mealtime, feeding themselves, eating and swallowing. The intervention was delivered in a well-lit, but quiet location in the nursing home. Television and radio were turned off, and doors and windows were closed to minimize distraction. During the intervention, participants sat up at 90 degrees in a chair with a table in front of them. We sat facing the participant in each session to ensure appropriate eye contact and clear communication. A timer was used to time the activity and SR intervals. Each session was conducted individually with each participant, and family members or staff from the nursing home were not present. The planned time of the intervention session was 30–40 min as mentioned earlier; however, the actual duration of each session varied depending on participant’s availability, mood and compliance behaviour. Sessions lasted between 40–60 min.

The intervention protocol aimed to focus on eating procedures and mealtime behaviour. During each session, we introduced and discussed the material needed in each activity and slowly and sequentially demonstrated the activity’s procedures. We then invited the participant to practice it the same way. In all activities, familiar food offered on the nursing home menu was used in the hope that sensory

TABLE 1 Items entered into economic costing

Item	Value
Nurse labour per hour (a)	£40.00 <sup>a</sup>
Length of intervention (b)	105 h
Total cost of intervention (c) [a/b]	£4200
Value of 1 unit change in EdFED (kcal) (d)	63kcal
Mean decline in EdFED score A1-A2 (e)	1.36
Change in kcal (f) [d×e]	86kcal
Cost per kcal [c/f]	£50.00 <sup>a</sup>

<sup>a</sup>Rounded up to the nearest £10.00.

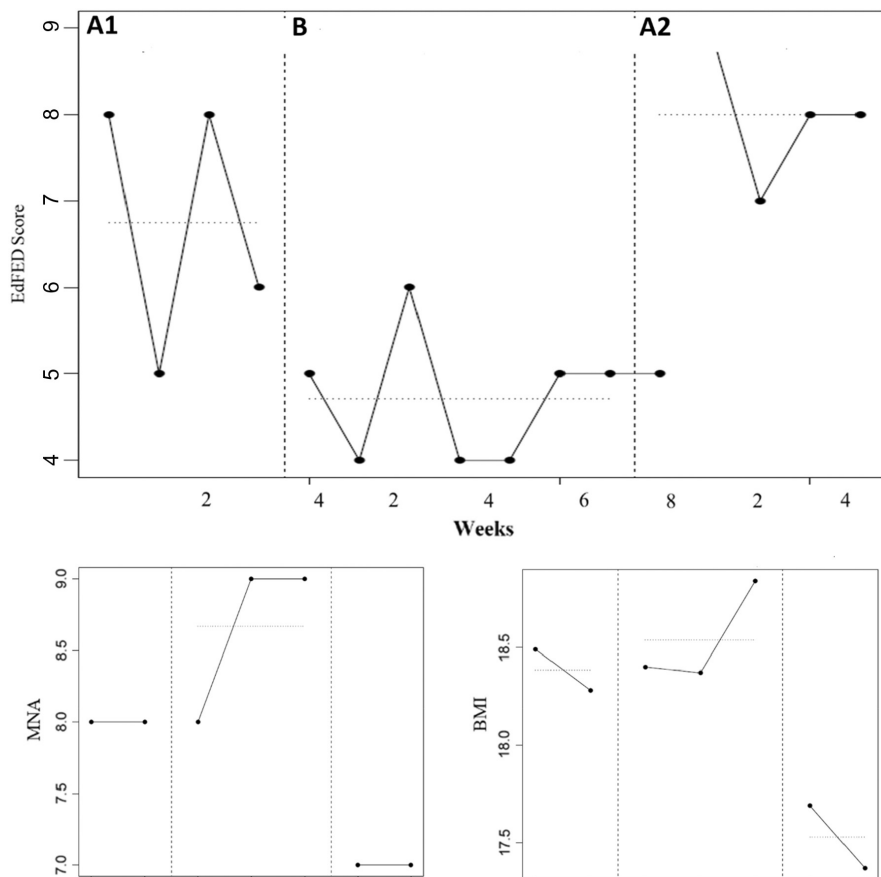


FIGURE 1 Participant 1 (male; 80years; length of stay 5 months; baseline EdFED = 5) single-case study analysis of effect of effect of spaced retrieval on EdFED (A1-B = 2.05), MNA & BMI scores in an A1 (baseline) B (intervention) A2 (withdrawal of interventions) experiment; Hedge’s  $g = 1.98$ .

stimulations from these foods would trigger the memory of pleasant experiences and then facilitate learning and initiate attending motivation for taking the food to eat. Each participant was required to complete three consecutive trials without error for each item. If the first immediate recall was correct, the time intervals was doubled to 1, 2, 4, 8, 16 and 32min. For deepening the memory, an interval of 32min beyond a 16-min interval was used. At each SR session, the participant was asked to recall only one piece of information.

During the SR time intervals, we prompted the participant to practice activities related to eating, such as scooping, pouring, squeezing and matching. In each SR session, only one type of activity was practiced. If a participant was not available at the scheduled time or was irritable or not willing to join the session, we approached the participant after some time when their mood stabilized.

2.2.3 | Ethics

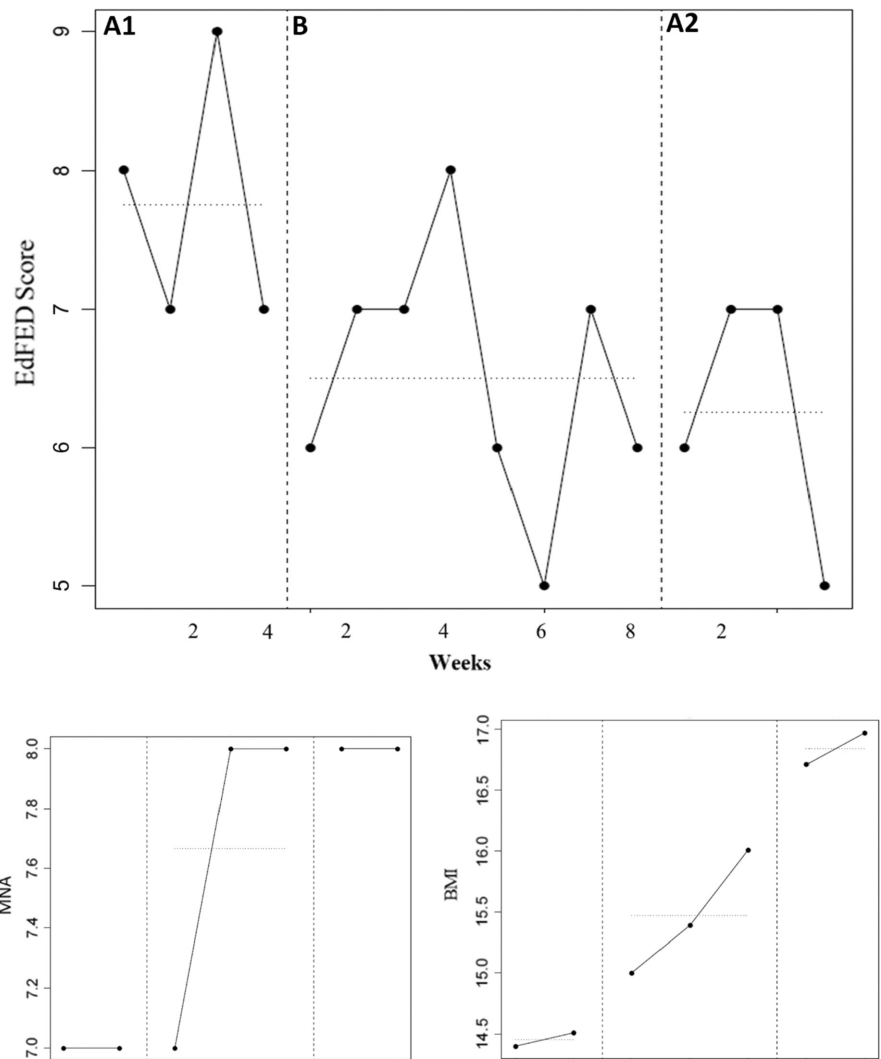
Research Ethics Committee approval for the study was obtained from the ethics committee of the University of Hull, and approval

was also obtained from by National Health Services Research Ethics Committee (NHSREC Ref 17/WA/0278).

2.2.4 | Outcome measures

*EdFED (Edinburgh Feeding Evaluation in Dementia; Watson & Deary, 1994) scale:* measures, uniquely, the behavioural/volitional aspects of mealtime difficulty in older people, as distinct from other aspects such as swallowing (Watson et al., 2001). The EdFED scale is recognized as the only internationally validated measure of mealtime difficulty in dementia (Aselage et al., 2011; Prince et al., 2014). The version used in this study measured mealtime difficulty with six items asking about relevant behaviours scored 0 (never) to 3 (always) with a range of 0–12.

*MNA-SF (Mini Nutritional Assessment-Short Form; Kaiser et al., 2009):* is a well-validated tool (Donini et al., 2016). It is designed specifically for the non-invasive assessment of nutritional status in older people and the revised and shorter tool called mini-nutritional assessment tool contains six questions and has three cut-off points for nutritional status. It allows quick identification of



**FIGURE 2** Participant 2 (female; 77 years; length of stay 42 months; baseline EdFED = 8) single-case study analysis of effect of effect of spaced retrieval on EdFED (A1-B = 1.8), MNA & BMI scores in an A1 (baseline) B (intervention) A2 (withdrawal of interventions) experiment; Hedge's  $g = 1.3$ .

those at risk of malnutrition in only 5 min. Anthropometric measures of mid-arm circumference and calf circumference were not used in this study as these are proxies which are incorporated in the MNA.

BMI (Body Mass Index; Keys et al., 1972): is a widely used measure of nutritional status calculated as the body weight (kg) divided by the height in metres squared and is recommended by the World Health Organisation (1995) and integral to the Malnutrition Universal Screening Tool (Stratton et al., 2006) which has been implemented in the UK National Health Service.

### 2.2.5 | Realist evaluation

In addition to visual inspection described above, a realist evaluation (Pawson & Tilley, 1997) was carried out to, systematically, find out if the intervention works. The data for this aspect of the evaluation were taken from the data collected about the individual participants in terms of age, diagnosis and length of time since diagnosis and time in the nursing home. We were specifically interested in exploring the following questions: What works? For whom? In what circumstances? by which we aimed to look at the successful interventions

and to see whether we could identify if there were any factors related to the individual participants and their individual circumstances which were influencing the outcome of the intervention.

### 2.2.6 | Economic costings

We conducted a cost consequence analysis of the intervention. A process or activity-based costing method was used to determine the cost of the intervention (Alrashdan et al., 2012; Lee et al., 2003). The details of which parameters were used in the economic costing are specified in the analysis below and provided in Table 1.

## 2.3 | Data analysis

### 2.3.1 | Single-case studies

Visual inspection is commonly used to analyse the data gathered in clinical research using a single-subject design (Kazdin, 2011). It is a non-statistical data analysis method in which data are plotted on a

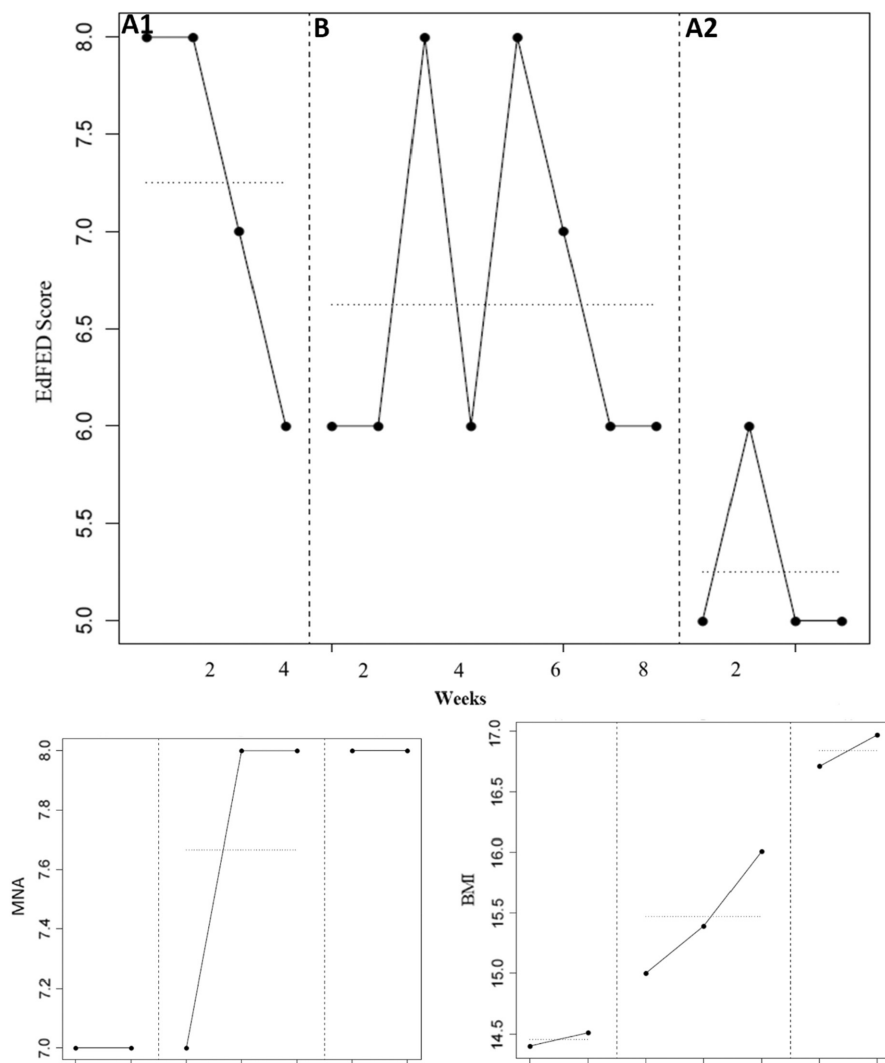
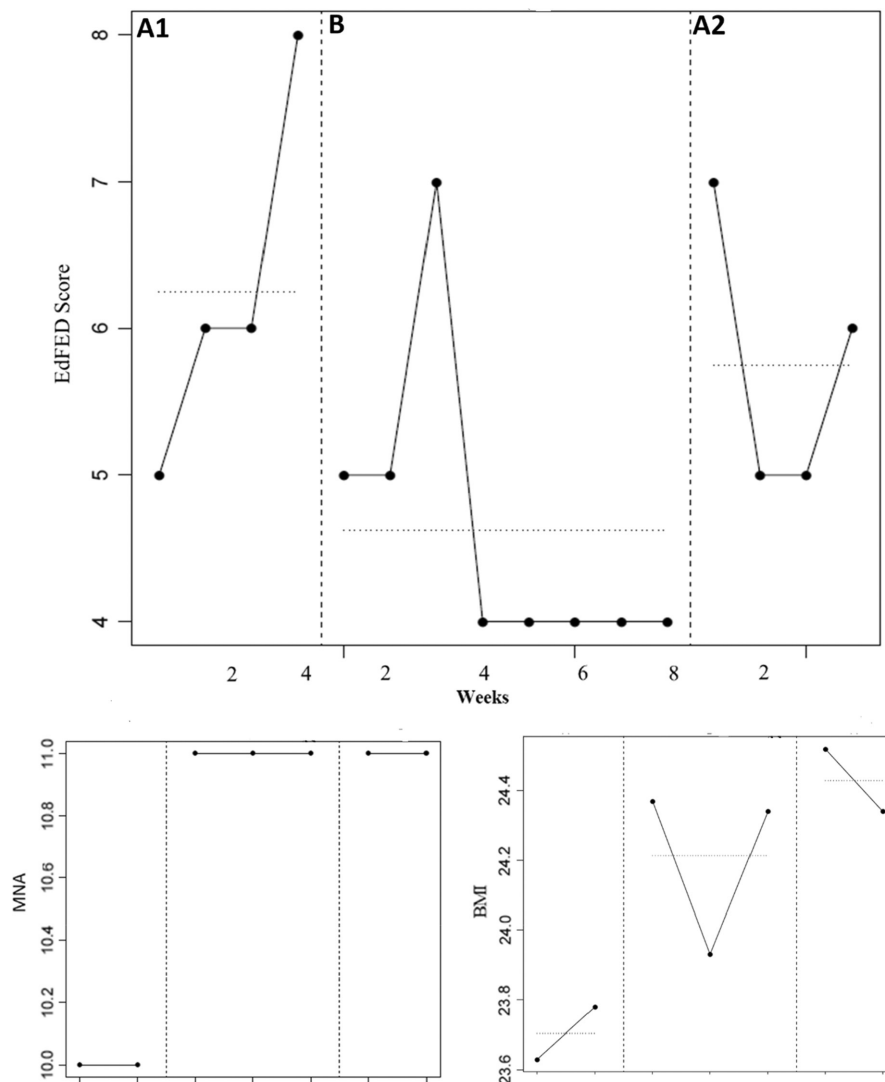


FIGURE 3 Participant 3 (female; 79 years; length of stay 7 months; baseline EdFED = 5) single-case study analysis of effect of effect of spaced retrieval on EdFED (A1-B = 1.25), MNA & BMI scores in an A1 (baseline) B (intervention) A2 (withdrawal of interventions) experiment; Hedge's  $g = 1.33$ .

**FIGURE 4** Participant 4 (male; 82 years; length of stay 30 months; baseline EdFED = 5) single-case study analysis of effect of effect of spaced retrieval on EdFED (A1-B = 0.17), MNA & BMI scores in an A1 (baseline) B (intervention) A2 (withdrawal of interventions) experiment; Hedge's  $g = 0.12$ .



graph with y axis representing the dependent variable and x-axis representing units of time (Zhan & Ottenbacher, 2001). When examining the changes of means, this is done to see if the dependent variable shows a change in the mean rate from the different phases and, if so, if this change is in the desired direction. If there is no change in level in the graph from the last day of the A1 to the first day of the A2, it will be shown as a level line. To create plots, a package available in the R Project for Statistical Computing (<https://www.r-project.org/>) called the R-commander package was used. It was used with the single-case data analysis (SCDA) facility to plot the outcome of the interventions with each participant. The use of R-commander and, specifically, the use of the SCDA facility is described in the literature (Bulté & Onghena, 2013). We used the facility to plot A-B-A experiments with central tendency (the mean) shown.

We calculated effect sizes for each participant (individual level analysis) and the combined effect sized across cases to obtain an estimate of the overall effect size (across-case effect size). A significance level of 0.5 was kept for all statistical analysis. Towards that end, we calculated Cohen's  $d$  for the mean change in EdFED score between phases A1-B and used this to calculate Hedges's  $g$  which

is a corrected effect size for small samples. Effect sizes are judged as follows: small, 0.2; medium, 0.5; and large 0.8. The Hedge's  $g$  is reported in the legends to Figures 1-8.

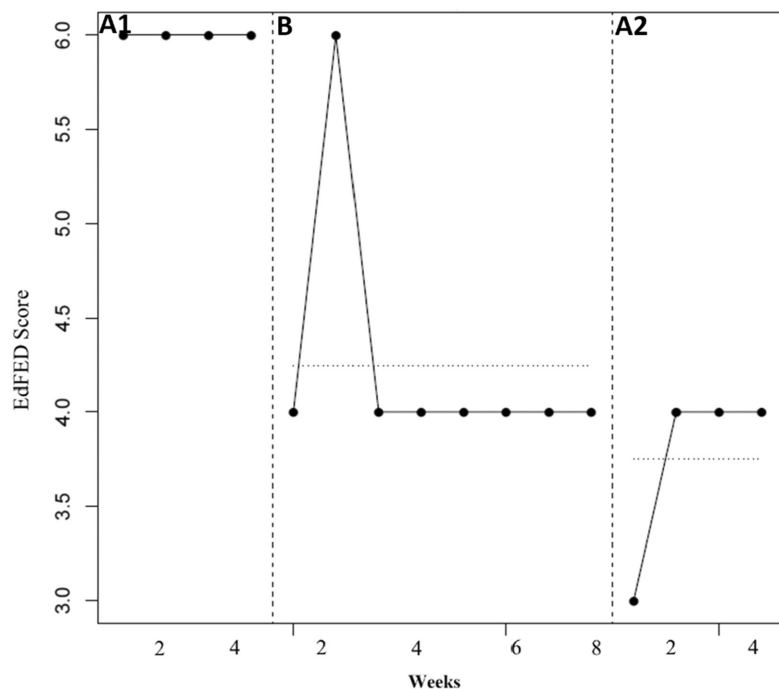
### 2.3.2 | Realist evaluation

We constructed context-mechanism-outcome (CMO) configurations. Specifically, the outcome (O) used here was EdFED score. The mechanism (M) was the spaced retrieval intervention. Using the contextual data (C) gathered about the individual participants, the environment and the circumstances of the interventions, analysis was performed to see whether any patterns emerge that link M to O (either successful or unsuccessful).

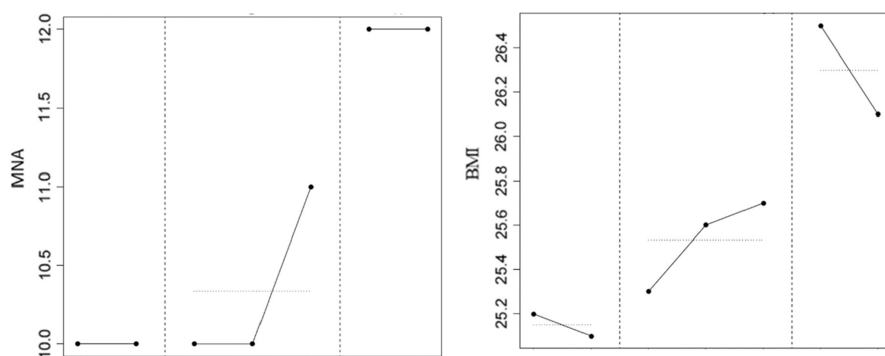
### 2.3.3 | Economic costings

Data on costs per healthcare worker were retrospectively collected using established micro-costing methods (Lee et al., 2003; Williams





**FIGURE 5** Participant 5 (female; 70years; length of stay 15months; baseline EdFED = 6) single-case study analysis of effect of effect of spaced retrieval on EdFED (A1-B = 0.62), MNA & BMI scores in an A1 (baseline) B (intervention) A2 (withdrawal of interventions) experiment; Hedge's  $g = 0.67$ .



et al., 2017). Using a midpoint pay range for nursing staff and care assistants of Band 5 working in the community, we calculated staffing costs per hour using data from the *Personal Social Services Research Unit* (PSSRU, 2020). Using the mean time of staff for the screening and other phases of the study, we calculated the cost of the intervention. These costs were related to the daily effects on calorie and protein intake resulting from the intervention as the effect of calorie and protein intake has been estimated per unit change in the EdFED score by Keller (2017). Using the mean calorie and protein intake changes, result from the intervention, the cost per unit change per day in calorie and protein intake was calculated. All costs are reported in pounds sterling for 2020.

### 3 | RESULTS

The results of the single-case studies are shown in Figures 1–8. The first observation is that the patterns of MNA and BMI scores mirrored the scores on the EdFED scale; therefore, we will focus here on interpreting the EdFED scores. In all eight participants, there was a positive effect of spaced retrieval and effect sizes were (with the

exception of Participant 4) at least medium, as indicated by the reduction in the EdFED mean score between phases A1 and B. In four participants, the effect was sustained into the third phase A2 (mean age 79; mean baseline EdFED 6.25; mean length of stay 23.25 months). In the remaining four, the EdFED score increased between phase B–phase A2 (mean age 77.75; mean baseline EdFED 6.5; mean length of stay 14.5 months). Given the universally reciprocal effect of spaced retrieval on the MNA and BMI scores, it is apparent that, in addition to alleviating mealtime difficulty, the intervention initially improved BMI and MNA in all participants. A realist evaluation to discern what worked for who and in what circumstances focussed on the sustainability of the intervention from phase B–A2, but no discernible pattern was visible by which we mean that the realist evaluation was not helpful in identifying characteristics or circumstances of the participants which contributed to the success of the intervention.

#### 3.1 | Economic evaluation

The cost of the intervention delivered by a Registered Nurse was calculated for a Band 5 Registered Nurse (PSSRU, 2020) using a

**FIGURE 6** Participant 6 (female; 70years; length of stay 15 months; baseline EdFED = 6) single-case study analysis of effect of spaced retrieval on EdFED ((A1-B = 0.62), MNA & BMI scores in an A1 (baseline) B (intervention) A2 (withdrawal of interventions) experiment; Hedge's  $g = 0.56$ ).

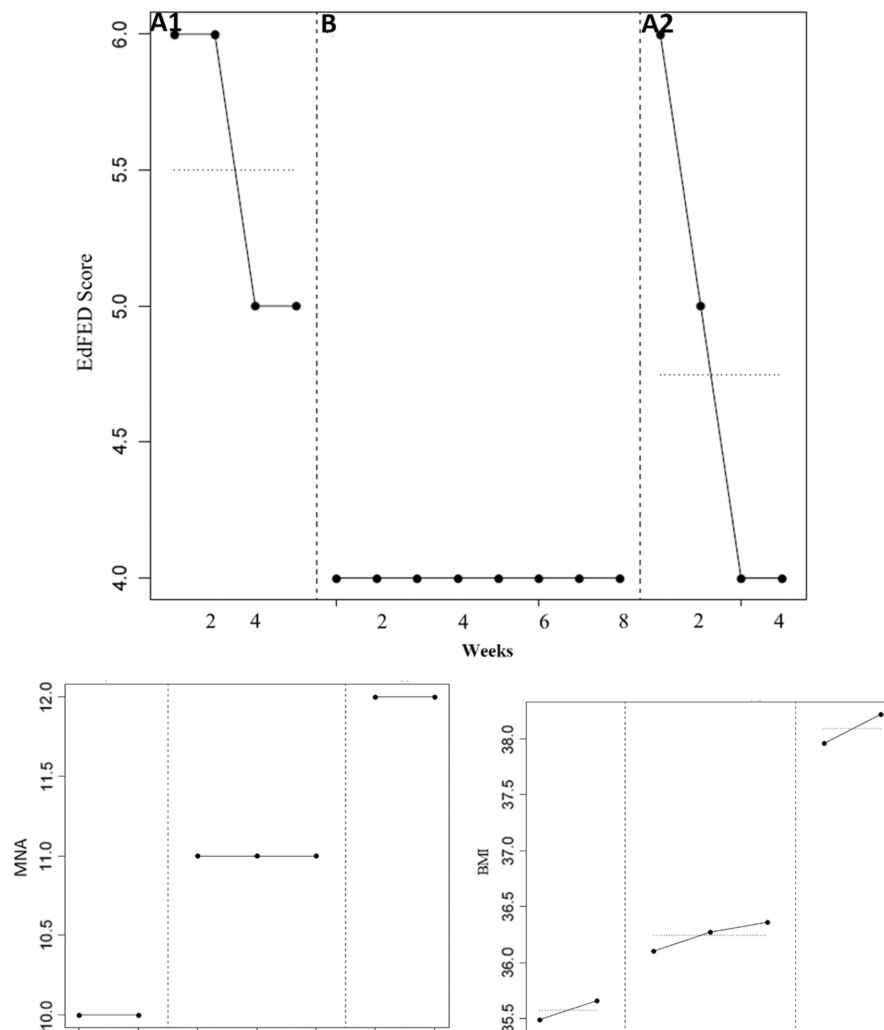


figure for salary plus oncosts rounded to £39 per hour over 8 weeks which involved (including screening and delivering the intervention) 105h = £4095. The mean decline in EdFED score between phases A1–B for the eight participants was 1.36. According to Keller et al. (2017), one unit change in EdFED score is equivalent to a gain of 63kcal meaning that the mean change in kcal was 86kcal (rounded up to the nearest kcal). Therefore, the cost of the intervention per kcal is £47.62 (Table 1).

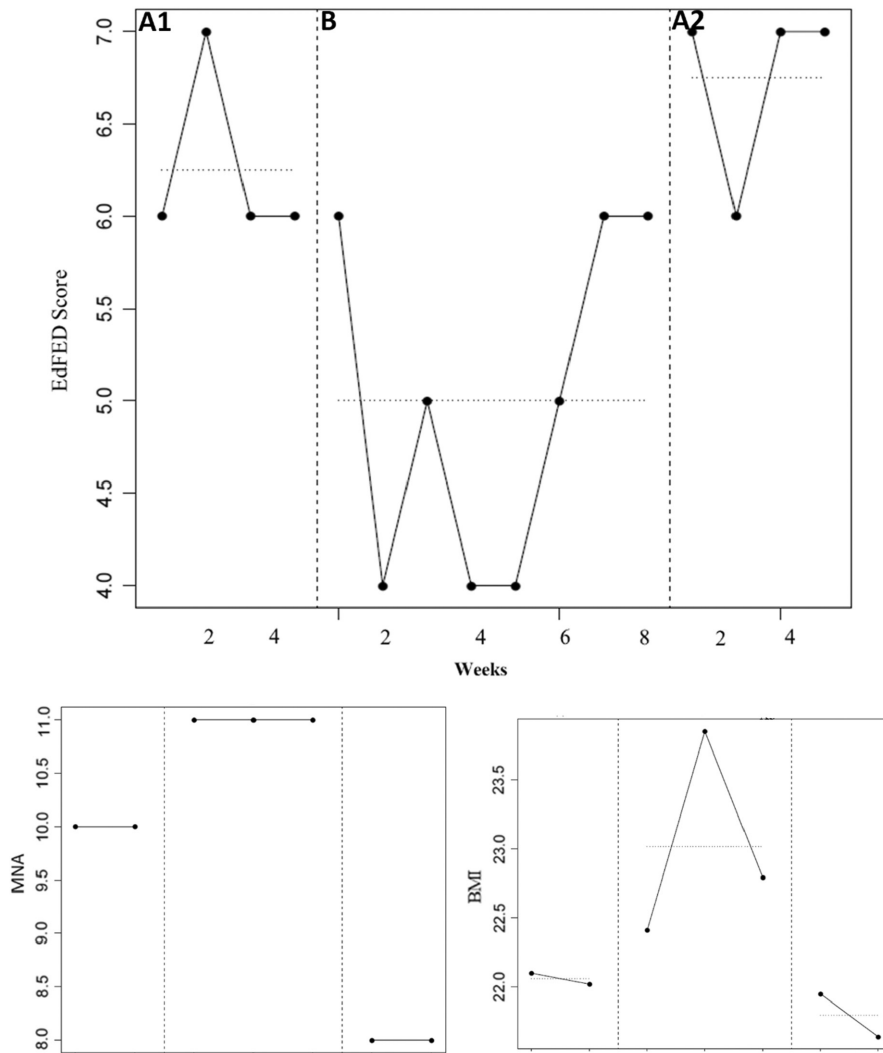
## 4 | DISCUSSION

This study was designed to test an intervention aimed at alleviating mealtime difficulty in older people with dementia. The intervention used spaced retrieval, already indicated to be effective in clinical trials (Lin et al., 2010, 2011) and used a single-case experimental approach. The rationale for the single-case approach was to enable more detailed analysis of the efficacy of the intervention with individual participants and to test the sustainability of the intervention. Ultimately, we may be able to design a targeted, short and cost-effective intervention and, towards that end, we also attempted to examine the intervention from a realist perspective (what works for

whom and in what circumstances) and evaluated the costs of the intervention in terms of its effectiveness at increasing calorie intake.

In all participants who completed the three phases of the ABA single-case intervention, the intervention was effective at reducing mealtime difficulty and in half of the participants the effect was sustained beyond the intervention phase. It is interesting to observe, even in the relatively short span of the intervention, that alleviating mealtime difficulty was paralleled by improvements in BMI and the MNA. These were not the primary outcomes of the study, but it is encouraging that gains in alleviating mealtime difficulty leads to gains in body weight and nutritional status. Keller et al. (2017) have already shown how increasing mealtime difficulty leads to reduced calorie intake and how a unit change in mealtime difficulty—measured using the EdFED scale—can be quantified in terms of calorie loss. Our study is not the first to demonstrate that mealtime difficulty can be alleviated, but it is the first to evaluate this in terms of change in calorie intake, as described below.

Based on the demographic data gathered from the participants, it was not possible to ascertain why the intervention was sustained in some participants and not others. Clearly, the demographic details of the participants which included length of stay and time since diagnosis may well contribute to the difference in sustainability of



**FIGURE 7** Participant 7 (female; 79 years; length of stay 8 months; baseline EdFED = 10) single-case study analysis of effect of effect of spaced retrieval on EdFED(A1-B = 1.62), MNA & BMI scores in an A1 (baseline) B (intervention) A2 (withdrawal of interventions) experiment; Hedge's  $g = 1.45$ .

the intervention between participants but no pattern was apparent in our sample where only eight participants completed the whole experiment. We can only speculate that with a larger sample and as further data are gathered then the relationship between the sustainability of the intervention and the characteristics of the participants may become clearer. It is notable that we did try to control as far as reasonably possible to control the conditions under which the intervention was administered, and the same person delivered the intervention throughout. A unit cost of the intervention per kilocalorie increased intake by the participants was calculated; however, without knowing the cost of malnutrition on a per calorie basis—information we were unable to obtain—it is not possible to comment on the cost-effectiveness of the intervention. However, the study results are the first to report unit costs of a nutritional intervention in this patient demographic. As such, these can be used for future comparisons and cost-effectiveness work.

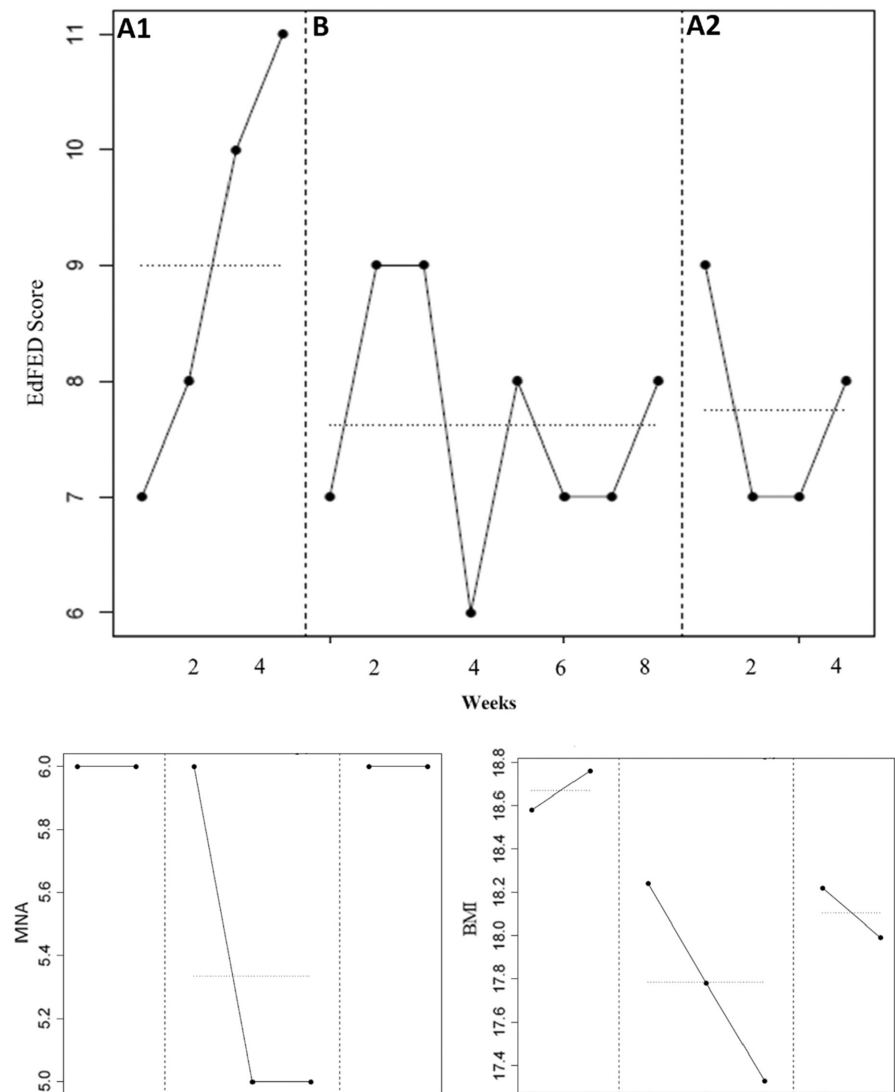
#### 4.1 | The single-case experimental approach

Clearly, the experimental method used in this study merits some attention. Compared with the clinical trial of the method, it is

not designed to study large groups and, as it requires repeated measure in each phase of the study, it is more labour-intensive. Nevertheless, it was sufficiently robust to enable us to see the transitions between phases of the study in individual participants. In addition, the single-case experimental method more closely relates to clinical practice than a clinical trial, which is always an artificially imposed situation. In a clinical trial, individuals are not monitored throughout and anomalous individual responses to the intervention (or being in the control group) are masked by aggregation of group results. Therefore, on the basis of our work, whereby all the participants responded positively to the intervention in the second phase of the experiment (the "B" phase of the ABA design), not all of these were sustained in the second "A" phase. As a result, we would recommend implementing the intervention a second time to investigate if that led to a sustained change in mealtime ability once the intervention was withdrawn. We consider that this could be the subject of a future study.

Regarding the analysis of single-case experiments. The visual inspection method is not free from criticism. The main criticism is the lack of specific decision rules, the requirement of a particular pattern of data (such as a stable baseline without trend in the direction of expected change) and the tendency to overlook small but systematic

**FIGURE 8** Participant 8 (female; 91 years; length of stay 29 months; baseline EdFED = 6) single-case study analysis of effect of effect of spaced retrieval on EdFED (A1-B = 2.75), MNA & BMI scores in an A1 (baseline) B (intervention) A2 (withdrawal of interventions) experiment; Hedge's  $g = 3.7$ .



effects. The visual inspection method is relatively subjective. The requirement for a stable baseline without a trend in the direction of expected change is often not realistic. We tried to address this using the mean values in each phase, but this method is very sensitive to outlying values, and with some participants, there was considerable variance in the phases.

Given the nature of single-case experiments, sample size is always problematic because data are not aggregated, and sample size determination derived from power analysis relate to group differences and effect sizes does not apply. No consensus on adequacy of sample sizes exists but compared with other published single-case studies, our sample size was similar and, in some cases (Olsson et al., (2014), bigger. Krasny-Pacini and Evans (2018) report that, typically single-case studies use one to three participants. The issue of determining how effective an intervention is, has been addressed by Michiels et al. (2019) who recommend repeated measurement episodes with the phases of the study randomized in each phase. In the timeframe of the present study, this was not possible, but it does indicate future lines of enquiry.

## 4.2 | Limitations

A limitation of the study is that intervention and the assessment were carried out by a single investigator. Future studies, with appropriate funding, could separate the intervention from the assessment of outcomes. In terms of the design, for which we have provided some advantages, clearly, there are some disadvantages. The design is, essentially, a within-subjects design and as such has lower external validity than a between-subjects design. The design, therefore, does not take into account any change in the circumstances where the intervention is carried out and, of course, the results have limited generalisability. There were difficulties in recruiting participants due to attrition from various causes and, notwithstanding the difficulties of estimating sample sizes for single-case experiments, the number of participants who completed all three phases of the ABA experiments was small. The study also focussed on a single intervention, and it was not possible to account for environmental factors which may influence its effectiveness. Finally, while we were able to calculate the

costs associated with the intervention, we were unable to locate data related to the cost of calorie malnutrition whereby the cost-effectiveness of the intervention could be evaluated.

## 5 | CONCLUSION

The main conclusion is that a spaced retrieval is effective at alleviating mealtime difficulty in older people with dementia. However, the sustainability of the intervention varies, and it is not clear which patient characteristics are related to the sustainability. This is worth investigating in future studies and, due to the large number of potential factors involved a larger number of participants would be required. Finally, the cost of malnutrition on a per calorie basis for older people with dementia should be estimated in order that the costs of the intervention can be compared.

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## CONFLICT OF INTEREST

The authors have no conflicts of interests with respect to the research, authorship and publication of this article.

## DATA AVAILABILITY STATEMENT

Data will be available on request

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