**Dementia-Friendly Book Groups in the Care Home: Can Quality of Life be Improved? A Randomised Clinical Trial**

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# Introduction

“The only end of writing is to enable readers better to enjoy life or better to endure it.”
― [Samuel Johnson](https://www.goodreads.com/author/show/22191.Samuel_Johnson) (1709-1784)

Reading is an important leisure activity with multiple health benefits, and the elderly are known to spend more time reading than any other age group. However, people living with dementia, often an older person’s condition, may find book reading difficult to access and enjoy because of progressive cognitive impairment. The benefits of reading for this population have not been widely studied, and therefore the authors of this proposal conducted a literature review, feasibility study, and pilot randomised control trial (RCT) plus qualitative linguistic study to investigate the practicalities of an extended study on the topic. These preliminary investigations have led to the main *hypothesis* of the proposed multicentre, international RCT, which is that *participation in a dementia-friendly book group enhances quality of life, thriving and cognition, particularly language, in residents with dementia at the residential aged care facility (RACF), compared to participation in activities as usual at the RACF.* The book groups are designed to be strengths-based for people with dementia, many of whom, we anticipate, can still enjoy sharing a 'good read'.

The Background Section below provides a comprehensive literature review, an account of the feasibility study and an account of the pilot RCT with qualitative evaluation, providing sound rationale for the full RCT.

# Background

Literature Review

### *The Recovery and ‘Discovery’ Model*

The recovery model in mental health care uses an approach that supports people to live as meaningful a life as possible despite persistent symptoms of illness. Recovery-oriented practice broadens the person-centred approach by promoting hope and eschewing therapeutic nihilism. This model is particularly salient for use in dementia care, as it acknowledges that recovery does not represent cure, but instead offers the opportunity for persons to regain confidence and identity within their communities and to exercise their choice to do things and develop relationships that give their lives meaning (Jacob, 2015). Current evidenced-based initiatives that aim to help people with dementia live as well as they can with the illness include using cognitive enhancing medications and psychosocial interventions. One such psychosocial intervention was the Meet Me at MoMA programme, where people with dementia were offered tours through the Museum of Modern Art in New York (Mittelman & Epstein, 2009). Professor Mittelman herself suggested that rather than use the term the ‘Recovery Model’ for dementia, the authors of this paper should use the term ‘*Discovery Model’,* as humans thrive on discovery throughout their lives, despite persistent symptoms of cognitive decline. (Personal communication at the Alzheimers NZ Conference in November 2016).

The most rigorously studied of the psychosocial interventions to date is Cognitive Stimulation Therapy (CST) which is a twice-weekly, seven-week manualised psychosocial intervention. This was found to have improved cognition measured by MMSE and quality of life measured by QoL-AD self-report, when compared to treatment as usual for community-dwelling participants with dementia. A Numbers Needed to Treat (NNT) analysis of CST compared favourably with antidementia drug trials for the cholinesterase inhibitors rivastigmine, donepezil and galantamine (Spector, et al., 2003). Maintenance CST improved QoL-AD self-report compared to control (Orrell, et al., 2014). CST is now recommended alongside cognitive enhancers in major guidelines for dementia treatment, including the NICE Guidelines (NICE-SCIE, 2006). Within academic research into psychosocial interventions for dementia, CST currently represents the ‘gold-standard’ by which to set experimental design and rigour.

Despite the evident benefits of CST, it has some limitations. These include the fact that it is designed for people with mild to moderate dementia and not for those who have more severe disease. It improved cognitive sub-scores on language function, but not on memory, orientation or praxis (Spector, Orrell, & Woods, 2010). A further limitation is that the manualised activities of CST are ‘imposed’ on the participants and so they are not necessarily activities that the person would choose for him or herself. It could be argued that facilitating access to community-based arts activities that the person once loved, or now chooses to take interest in, promotes recovery-oriented (and ‘discovery-oriented’) practice more fully than CST.

A recent systematic literature review by Young et al summarised the findings of community-based arts interventions on cognition in people living with dementia. Seven of these related to the performing arts; seven to the visual arts; and three to reading, or literary arts (Young, Camic, & Tischler, 2016). All studies suggested an impact on communication skills and the studies involving reading reported additional enhancement of memory recall (Holm, Lepp, & Ringsberg, 2004) (Phillips, Reid-Arndt, & Pak, 2010) (Billington, Carroll, Davis, Healey, & Kinderman, 2013). However, Young et al critically concluded that arts intervention research suffered from deficient samples, control groups, measurement tools and intervention documentation. . This is consistent with the findings of the US National Endowment for the Arts in their 2013 report (US National Endowment for the Arts, 2013). Young et al maintain that the quantitative studies they examined lacked power and case control, while the qualitative studies gave insufficient detail of how analyses were conducted. Most studies were restricted to people with mild to moderate disease and recommendation was made to extend assessment to people with more severe illness (Young, Camic, & Tischler, 2016).

### *Benefits of Reading for Adults*

In 2006, a study in the UK based on 4000 adults found that more than four-fifths of them enjoy reading, rating it more important than watching television, with women rating it more important than sex (Rumbold & Clark, 2006). In the US, retirees spend more time reading for pleasure than any other age group, 30 minutes per day for those over 65 years, and one hour per day for those over 75 (Godbey, 2013). Author of *Lost in a Book: The Psychology of Reading for Pleasur*e (Nell V. , 1990), psychologist Victor Nell wrote that ludic reading (reading for pleasure) is a form of play which allows us to ‘experience other worlds and roles in our imagination’ (Nell V. , 1988). This important pastime is far from a passive activity; rather it is a hermeneutic, interpretative and creative activity, shaped by our previous memories and experiences (Graff, 1992). Reading creates connections and conversations with the text and with our imaginations; it lulls and surprises us.

But despite the perceived advantages of reading, avid ludic readers may sometimes be labelled sad, lonely individuals who find social interaction difficult. In fact, with personality traits controlled for, Mar et al (Mar, Oatley, & Peterson, 2009) suggested that adults who regularly read narrative fiction have enhanced social empathy and Theory of Mind, and more social supports. Theory of Mind is a construct that describes a key aspect of social functioning, which involves the ability to understand, predict, and infer other’s mental states, such as thoughts, beliefs, and feelings (Baron Cohen, Leslie, & Frith, 1985). Individuals in the Mar study who primarily read non-fiction were more stressed and lonely, with negative self-perceptions of belongingness. more recent study suggested that lifetime exposure to fiction predicts better scores on Reading the Mind in the Eyes Test (RMET) (Baron-Cohen S. , Wheelwright, Hill, Raste, & Plumb, 2001) (Baron-Cohen, Wheelwright, & Jolliffe, 1997), a valid measure of Theory of Mind. Using functional MRI scanning, when subjects read literary fiction, brain areas such as dorsomedial-prefrontal cortex (dmPFC) and the left temporo-parietal junction (TPJ) are preferentially activated to exercise mental simulation capacities. These are the same networks recruited during social cognitive tasks (Panero, et al., 2016). Hence, it is conjectured that reading helps the individual to “conjure up experiences outside of their local experiences, such as thinking about the future or the past, mentally constructing places and spaces, imaging hypothetical events and thinking about another’s perspective”(Tamir, Bricker, Dodell-Feder, & Mitchell, 2016).

In “Shall I compare thee: The neural basis of literary awareness, and its benefits to cognition”, functional MRI scanning is used to explore the effects poetic works on brain networks. Poems with unexpected last lines activated not only the predicted areas of the default mode network (DMN, including the dmPFC and posterior cingulate cortex), but also areas recruiting the salience network (SN, such as the dorsal caudate) and the central executive network (CEN, including the dorsolateral Prefrontal Cortex dlPFC) (O’Sullivan, Davis, Billington, Gonzalez-Diaz, & Corcoran, 2015). Literary awareness moved the mind from passive self-referential imaginings to more active awareness of ‘other’, allowing the reader to be transported ‘to some other place’…, to be ‘removed from themselves’ as Nell suggests (Nell V. , 1988, pp. 49-50). This can occur without stepping out of the reader’s own home or RACF.

Some researchers suggested that book reading not only makes us nicer but smarter (Paul, 2013), and that these benefits underlie the survival advantage that book readers have over non-book readers. A large, 20-year longitudinal study from Yale, “A chapter a day: association of book reading with longevity”, showed a 20% reduction in mortality for those who read books, on average of just 30 minutes a day, compared to non-book readers (reading only newspapers, magazines and journals). After controlling for multiple co-variates, including baseline cognition and education, mediation analysis suggested that this survival advantage was gained through the effect of book reading on maintaining cognitive status over the study period (Bavishi, Slade, & Levy, 2016).

But is there any difference between reading airport blockbusters, by authors such as James Clavell and Robert Harris, and reading the classics; books which have stood the test of time? It is possible that there is. Keidel and Davis used brain imaging to explore the effects that ‘serious literature’ had on cognition. Using functional MRI, they captured the ability of Shakespearean play on words to activate wider brain networks than typical language tasks, creating what the authors called “a kind of neurological tempest” (Keidel, Davis. P M, Martin, & Thierry, 2013). For example, in Act 1 Scene 2 of *The Taming of the Shrew*, Petruchio, instead of saying “ I come to find a rich wife in Padua”, puts it far more succinctly and poetically: “I come to wive it wealthily in Padua;”. Similarly, Professor of Rhetoric Michael Burke explored these themes widely in a scholarly work *Literary Reading, Cognition and Emotion: An Exploration of the Oceanic Mind* (Burke M. , 2011), taking the reader through the ‘oceanic mind’ created by the rhetorical language of F. Scott Fiztgerald’s *The Great Gatsby*. Burke wrote that“literary style is a physical phenomenon” and “the neural pathways in the brain of the avid literary reader will be stimulated and shaped by repeated exposure… incrementally altering muscle tone and neural wiring, strengthening and increasing speed in synaptic pathways, improving their capacity and performance” (Burke M. , 2013).

Stanovich, comparing the effects of reading on the young and old, suggested that exposure to print can help to compensate for the deleterious effects of ageing (Stanovich, West, & Harrison, 1995) (Stanovich, Cunningham, & West, 1998). If this is true, does a habit of book reading contribute to *cognitive reserve*, the brain’s resilience to pathological damage? The well-known ‘Nun Study’ by Professor Snowdon followed up 678 Catholic sisters from 1991, analysing data from convent archives, annual examinations of the nuns aged 75 to 102 years, and brain specimens once they had died. In a 1996 report, Snowdon showed a strong association between higher linguistic ability in early life, based on idea density and grammatical complexity seen within hand-written autobiographies by the nuns in their youth, and higher cognitive ability and protection against clinical symptoms of Alzheimer’s disease despite pathological brain changes 58 years later. This association held after education and occupation were controlled for (Snowdon, et al., 1996).

In a case study of healthy aging, Snowdon described how despite Sister Mary showing extensive neuropathology of Alzheimer’s brain changes on autopsy at age 101 (atrophied, low weight brain with plagues and tangles of Alzheimer’s), she maintained good cognitive functioning up until death, without a diagnosis of dementia. Snowdon described her as follows: “She had a big open mouthed smile, soft facial skin, and eyes that radiated joy and peace. Her trademarks were a long beaked green visor she wore to protect her eyes from glare, and a warm and hearty cackle of a laugh that boomed out of her room at all hours of the day and night. In her "\’retirement’ she continued to be active in her community and concerned about world events. She was an avid reader and was often seen poring over newspapers and books with her magnifying glass” (Snowdon D. , 1997).

Yaakov Stern developed the theory of cognitive reserve in aging (Stern, 2012). There is increasing evidence that some people, like Sister Mary, can tolerate age-related brain changes and Alzheimer’s pathology and still maintain cognitive function, and that these two are not linearly related (Snowdon D. A., 2003). Many studies cite the positive effect that education has on increasing cognitive reserve and protecting against dementia. Sister Mary was a life-long reader but not particularly well educated. Some studies have linked literacy and book reading to cognitive reserve and protection from dementia risk, when education was controlled for. A recent prospective cohort study suggested that limited literacy correlated to dementia risk. 25.5% of those with limited literacy (less than 9th grade reading level) developed likely dementia over the 8 year follow up of the study, as compared to 17% with adequate literacy. Interestingly, in this study, education was not associated with likely dementia risk (Kaup, 2014). In a 2016 South Korean study, 16% of the total number of dementia cases could be attributed to illiteracy, and suggested that if illiteracy was eradicated this would save the country an estimated 52 billion US dollars in medical care for dementia sufferers (Wilson, et al., 2013). In the Rush Memory and Aging Project, early and late life cognitive activity, including reading books, visiting the library and writing letters, together accounted for 15% of the residual variability in cognitive function after adjusting for neuropathology in the brain. The authors hypothesised that cognitive activity, such as book reading, could support cognitive reserve to counterbalance cognitive loss associated with neuropathologic burden. In a study of people living beyond aged 90, the lifestyle factors of going to church/synagogue and reading or having stories read aloud during the nonagenarian years were the most significant lifestyle factors to lower risk of developing dementia over the next five years (Suh, 2016). This is interesting because both church and synagogue services largely consist of the repetition of well known ‘stories’ in the form of bible and torah readings.

### *Benefits of Reading for People with Dementia*

There is clear evidence, then, that reading probably has wide benefits for people in general, but what about specific benefits for people living with dementia? There is only one review of a reading intervention in Young’s systematic review of psychosocial interventions (Young, Camic, & Tischler, 2016) for people with dementia. This is a collaborative research project with University of Liverpool’s Centre for Research into Reading, Information, and Linguistic Systems and The Reader Organisation (Billington, Carroll, Davis, Healey, & Kinderman, 2013). The evaluation uses the ‘Get into Reading (GiR)’ model based on shared group reading, where material is read aloud and open discussion follows. Davis and Billington (personal discussion at mentoring meeting at University of Liverpool, 2015) emphasize the value of reading short items of poetry aloud for people with dementia, as the rhythm and rhyme of the material seem to maintain concentration and interest.

The study design, with 61 people with mild to moderate dementia and 20 carers, used a mixed-method approach, observing for changes in behaviour and mood with the Neuropsychiatric Inventory Questionnaire (NPI-Q) and qualitative thematic analysis. NPI scores were lower (hence fewer psychiatric problems) during the reading groups versus baseline measures; however, NPI measures were low at baseline, sample size was small, and there was no case control, reducing the statistical validity of the quantitative component of the study. Quality of life measure with DEMQOL-Proxy collected monthly during the six-month study showed an increase in scores once the reading groups begins, with maintenance once the activity finished. However, the sample size was small and generalisability limited.

The following themes were identified through qualitative analysis: enjoyment, authenticity and meaningfulness of reading-group experience; renewed sense of personal identity; enhancement of social relationships; and finding the value of an activity that can be sustained by family members. Professor Philip Davis concluded that “there are strong indications that the power of literary language can both trigger relevant past experience and prompt fresh acts of thought” (Billington, Carroll, Davis, Healey, & Kinderman, 2013). The authors recommended designing a randomized controlled trial (RCT) to test the value of reading as a psychosocial intervention for people with dementia, while including a qualitative component to capture important psychosocial nuances. Thus, there do appear to be benefits in bibliotherapy for people living with dementia, but does this imply that textual adaptations should be made specifically for them and if so, what should they look like?

### *Designing Dementia-Friendly Books*

People living with dementia may find lone and group reading difficult to access and enjoy because of specific cognitive impairments (Papathanasiou & Coppens, 2017). Carers frequently offer people living with dementia, children’s books to read. This is probably done in the belief that dementia sufferers’ reading ability diminishes along with their memory loss, in a ‘de-developmental model’ of regressed linguistic functioning, and this diminished ability might be on a par with that of a child learning to read. But this may be considered infantilizing by the readers.

But linguistic studies have suggested that for common dementia types, such as Alzheimer’s disease (AD) or vascular dementia (VA), language comprehension might be compromised by “attenuated span capacity, difficulty focusing attention, encoding and activation of long-term knowledge, rather than from loss of linguistic knowledge” (Bayles, 2003). The National Adult Reading Test (NART) is a measure to test a person’s premorbid literacy attainment after they have suffered some brain insult, such as AD. The NART administrator asks the individual to read a list of 50 words that have irregular spelling-to-sound correspondence, such as ‘soot’ or ‘height’. Results from NART correlated strongly with pre-morbid educational attainment and intelligence, and possibly cognitive reserve (MacPherson & al., 2017). People with mild to moderate AD generally retained the linguistic knowledge they previously gained in their reading life; their NART scores were not significantly worse than adult controls, and were significantly better than children’s scores (Cummings, Houlihan, & Hill, 1986) (Leff & Starrfelt, 2014).

People with mild to moderate AD have retained ability to recognise the meaning of low-frequency words (words that are not commonly used, such as ‘brisk’), especially if they were used in a familiar context such as a well-known story (Bolata, Burgess, Cortese, & Adams, 2002). Hence ludic readers who have now developed dementia may not need to have the vocabulary of once-loved literary classics ‘dumbed’ down, as they are likely to have retained understanding of irregular syntax and low frequency lexis. Children’s books, or books written for the adult learning to read English as a second language (which rely on high frequency words and simple syntax), may sometimes be over-simplified and infantalising for the skilled English reader with dementia. Two co-investigators in the proposed multicentre RCT have recently published an article challenging the ‘regression hypothesis’ of dementia, particularly in respect of choice of literature and reading materials. Please see their article, as attached in Documents. (Rimkeit & Claridge, 2017)

Several researchers have provided practical recommendations for making text more “aphasia-friendly”, or “dementia-friendly”. Bayles recommended avoiding overuse of pronouns that require remembering antecedents. She also recommended pictorial reminders to provide contextual support. Providing repetition of plots or storylines assisted with learning. Priming with related words or familiar story was helpful, as priming was seen as an unconscious form of memory that was relatively spared in AD. Adaptations should rely on recognition where possible rather than recall and avoid demanding multitasking to reduce encoding, storage and coding demands40.

Because people with AD may have visual deficits in spatial contrast, it improved readability if there was strong contrast between the text characters and the background. In a test using 60 one-syllable words, when spatial contrast was high (84 or 98% on the Michelson contrast scale) then accuracy in reading and pronouncing the words for people with mild or moderate Alzheimer’s disease was about the same as for normal controls. When contrast was 69% or less, then word extraction was slow and inaccurate for people with dementia (Gilmore, Groth, & Thomas, 2005). Rose, Worrall and McKenna’s research on producing ‘aphasia-friendly’ health literature for stroke patients (some of whom will have VD) recommended use of an optimum amount of ‘leading’, or white space between lines of text, set at about 1.5 line spacing. Broad line spacing of 3.5 was just as difficult to read as single spacing. They recommended a large font, from around 14 to 30 size, but not larger. Their participants found that illustrations made the information “more interesting” but not necessarily more understandable. Graphics with colour and clarity, such as a photograph, were more helpful than black and white drawings or pictographic symbols. Regarding length of health literature booklets, most participants in Rose’s study preferred the longer booklets (26 or 38 pages), as long as the text was formatted with the guiding principles above (Rose, Worrall, & McKenna, 2003).

Ostrowski and Dixon, experienced speech and language therapists, published an article in 2016 outlining their recommendations on how best to adapt reading material for people with dementia (Ostrowski & Dixon, 2016). Theirs, they state, is an “observational study”, though the article fails to outline their methodology. They recommended practical adaptations to reading material, including the use of thick and stiff paper, easy to turn and handle; matte finish paper with jet black ink and high brightness; thin books of about 20 to 30 pages; uncluttered design; ample white space; large print; sans serif font; photographic illustrations; and simplification of syntax without necessarily simplifying vocabulary. They produced a series of adapted books for people with dementia based on selected non-fiction themes (see [www.reading2connect.org](http://www.reading2connect.org)), along the precepts which they recommend, but they do not explain the basis on which these recommendations are made, nor why their reading materials are exclusively non-fiction.

### *Conclusions drawn from Literature Review*

Cognitive stimulation therapy has been proven to improve cognition in language in people living with dementia, as Spector et al have shown. It has also been demonstrated that reading has a positive effect on life expectancy in general, by maintaining ‘cognitive reserve’, and suggests that reading contributes to retarding the ‘deleterious effects of ageing’ (Stanovich, West, & Harrison, 1995) by supporting the brain’s resilience to pathological damage. This appears to be borne out by Snowdon’s ’Nun Study’ (Snowdon D. , 1997). Yet the study by Billington et al in Liverpool on the effects of shared poetry readings for people with dementia (Billington, Carroll, Davis, Healey, & Kinderman, 2013), and the feasibility study by co-investigators Rimkeit and Claridge (with data of the Pilot RCT and Qualitative study by the co-investigators still to be analysed) appear to be the only study addressing the positive effects of reading on the quality of life of people living with dementia. Regarding specific adaptations for this audience, Bayles’ advice to rely on recognition rather than recall is wise (Bayles, 2003). As far as the design of these books goes, several precepts have been proposed, notably by Rose et al (Rose, Worrall, & McKenna, 2003), and Ostrowski et al (Ostrowski & Dixon, 2016), but we can find nothing written about adapting classic fiction for this audience apart from our own research ( (Rimkeit & Claridge, 2017).

From the research findings outlined above, it appears that literary fiction, as opposed to expository non-fiction, is more likely to excite the mind with ‘discovery’ to produce more wide-ranging cognitive benefits and improved quality of life (Burke M. , 2011), (Keidel, Davis. P M, Martin, & Thierry, 2013) (Rimkeit & Claridge, 2017). With 47 million people now experiencing dementia, many of whom have been avid readers throughout their lives, enhancing access and enjoyment to literary fiction through facilitated book groups may prove to be a valid and effective psychosocial intervention.

# Proposed Research Plan

The Investigators of this project have begun a three-step process to answer the question: Can participation in a book group, appropriately facilitated, improve~~d~~ the quality of life of persons living with dementia?

Step 1, the Feasibility Study**.** In 2015-2016, Drs Rimkeit and Claridge completed a feasibility study to discover the attitudes and opinions of people living with dementia towards reading targeted adaptations of classic literature and discussing them in book groups. The results of the feasibility study are given in the following section and in the published article by the co-investigators (Rimkeit & Claridge, 2017), attached under Documents.

**Step 2: The Pilot RCT.**

The pilot RCT, completed in 2017 by Drs Sim, Rimkeit and Claridge, investigated the question: Can an appropriate Book Group intervention be carried out and evaluation of Quality of Life appropriately assessed using a single-blind Randomised Trial in the population of interest, persons living with dementia (PLWD). The methods and procedures for this protocol are given in the section after the discussion of the feasibility study.

**Step 3: The full RCT** (to start in 2018). The research question of the full RCT is whether or not the book group intervention, as adapted using the information from steps 1 and 2, results in an improvement of Quality of Life in persons living with Dementia. Dr Dalice Sim of University of Otago, Wellington, New Zealand, will be the coordinating investigator (CI) of the multicentre, international RCT. Prof David Edvardsson at La Trobe University, Melbourne, Australia, and Profs Josie Billington and Philip Davis at Liverpool University, UK, have expressed interest in heading up the RCT in their regions, as part of the international consortium conducting this RCT. Bupa Care New Zealand, Australia and UK are potentially providing resource in kind for the RCT, as outlined in this protocol.

## Step 1: Feasibility study carried out in 2015-2016 by Dr Rimkeit and Dr Claridge

### *Introduction*

The feasibility study as described below, and the results of this, plus the conclusions from the literature review, provided the rationale for the pilot study and full RCT. Please also refer to the published report on this study (Rimkeit & Claridge, 2017).

### *Methods*

Participants

The participants were 7 people (4 male) with median age of 81, range from 66 to 84 years, diagnosed with dementia by a medical practitioner. Four lived in community with family and three in a secure dementia unit at the Residential Aged Care Facility (RACF) where the focus groups took place. Their level of linguistic competence was assessed during individual interviews where the researchers sought participants’ consent, and talked to them about the study and about what they liked to read. Their avowed reading preferences were for fiction over non-fiction, and they liked action stories best, then crime, romance and mystery. Biography was most popular in non-fiction.

### *Procedure*

HDEC approval to conduct the study was sought, and was granted on 18 August 2015, and the study commenced in November 2015. Participants were recruited by means of posters put up at day centres and RACFs in the lower North Island of New Zealand. The researchers created and published a version of Charles Dickens’ *A Christmas Carol (CC)*, labelled Book C in the study, with text simplified to Flesch Kincaid US Grade 2, and the first 1000 words in Lextutor (Cobb 2015). Illustrations were procured from vintage *CC* books. (Kincaid, 2017) The original CC was selected because it is a relatively short, heart-warming tale, written in Dickens’ inimitable, humorous style, and was likely to be familiar to the participants. A comparison between the language in the three versions is shown in Table 1 below. It indicates that there was not a great difference in the language complexity of the original Dickens (Flesch Kincaid Grade 6) and the version supposedly simplified for children (Flesch Kincaid Grade 5). Interestingly, as can be seen, the children’s version had the greatest percentage of words outside the first 2000 most frequent words in the British National Corpus. The adapted version was considerably simplified to Grade 2. The adapted version and the original showed approximately similar ratios of words in the frequency categories, showing that the lexis in the original Dickens was not much more unusual than that in the adapted version, although the syntax was at a higher level.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Flesch Kincaid | Lextutor word frequency analysis  |
| **Text Version** | **Word number** | **FK Ease of reading****level** | **FK** **US school Grade** | **Ist 1000 words** | **2nd 1000 words** | **Academic Word list**  | **Words outside the other categories** |
| A (Children’s) | 750 | 5 | 5th | 68.8% | 11.65% | 1.13% | 18.42% |
| B (original) | 32,398 | 6.4 | 6th | 81.12% | 6.60% | 1.42% | 10.86% |
| C (adapted) | 1496 | 2.4 | 2nd | 82.85% | 7.25% | 0.11% | 9.71% |

Table 1:Analyses of texts used in pilot study

<http://www.readabilityformulas.com/free-readability-formula-tests.php>

*McClure G (1987). "Readability formulas: Useful or useless. (an interview with J. Peter Kincaid.)". IEEE Transactions on Professional Communications.****30****: 12–15.*

The adaptation (Book C) was given to the participants at the initial interview, together with a large print, non-illustrated book with the original *CC* text (Book B) and a commercially produced, illustrated children’s adaptation of *CC* (Book A). The participants were asked to read from each of Books A, B and C before participating in a focus group two weeks later. They were also, with the assistance of carers, asked to keep a daily diary, logging what they read each day and how much. However, in no case was this achieved, so the results of the feasibility study are based solely upon the information gleaned from the Focus Groups.

Focus Group 1(FG1) consisted of four community participants (FG1:1, FG1:2, FG1:3 and FG1/2:4) and Focus Group 2 (FG2) of three participants from the dementia unit (FG2:5, FG2:6, FG2:7), with a fourth from the community (FG1/2:4), attending both groups due to travel arrangements. The focus groups followed a semi-structured interview format. The focus group meetings were audio-recorded with a Sony icd-px440 with 4gb of memory which provided satisfactory discrimination of participant voices, and then transcribed by researcher GC. Data was entered into NVivo and coded by both authors using Interpretative Phenomenological Analysis (IPA), which attempts “to get as close as possible to the personal experience of the participant, but recognizes that this inevitably becomes an interpretative endeavour for both participant and researcher.” (Smith, Flowers, & Larkin, 2009) (Smith, 1994, pg 37).

### *Findings*

Because no diaries were kept of the reading process, and because of the cognitive limitations of the participants, it was impossible to estimate how much, if any, lone reading had taken place prior to the Focus Groups. Therefore, all the data reported in this study is a result of the Focus Groups, and therefore reflects shared reading, such as would take place in a book group situation.

The themes of the Focus Group discussions can be divided into three main areas, which were general attitudes to reading, preference for the original language of Dickens over an adaptation, and recommendations from the participants for future texts. These are summarised in Table 2 below:

|  |  |  |
| --- | --- | --- |
| **Super-ordinate themes** | **Sub-ordinate themes** | **Examples from data** |
| General reading attitudes | Interest in reading  | FG:1 C said: *“I’ve always been a voracious reader. Books always took me to another adventure, another part of the world, a new topic to understand.”*When the researcher G said: Books can be very comforting,.. very important, FG1 : F said, *“Especially if you’re ill for a long period: when I was about 14 I was bedridden for about 3 months and I read an awful lot*.” |
|  | Interest in book groups | When asked if they would like to join a book group FG2:M stated: *“That’s a great idea. We could descend on them with our ideas.”* |
|  | Family attitude to reading | FG1: F said: *“When we were younger, there were always books around.”*But FG1: Y said*: “It [reading] wasn’t part of family life. Our house was always full of people and there was no peace and quiet.”* |
|  | Liveliness of discussion | FG1/2:R, who attended both groups, was asked which had been the more lively. He replied emphatically,’Focus Group 2’. This was the people from the dementia unit. |
|  | Recall | FG2:L recognized Book C when shown an illustration of Scrooge’s door knocker which turned into Marley: *“Oh that might be it. That might be the book I read this morning. That might be it.”* |
|  |  |  |
| Preference for original Dickens | Dislike for “over-simplifying” | FG1:C commented that Book A was *“too simple. It lost Dickens. It tells the guts of the story but you lose the voice of Dickens. You don’t have access to his imagination.”* |
|  | Enjoyment of text | FG2:L said: L: *“Yes, yes, Marley was dead. It’s lovely.. Marley was as dead as a doornail.”* |
|  | Language play generated | Reading: “Everyone knew old Ebenezer Scrooge was the most tight-fisted miser you could meet, a squeezing wrenching grasping scraping clutching covetous old sinner.” In response to this:FG2:L: *“Piss off, you old bastard!”*FG2:M: *“Oh, yes, I love it.”*FG2:L: *“Explain covetous to me.”*FG2: M: *“Covetous is when you take something and you keep it!”*FG2:L: *“And you shouldn’t do that!”*FG2:M: *“ Never!.”*In response to: “No one ever stopped Scrooge in the street to say My dear Scrooge, how are you?”FG2:L: (continues her involvement with Scrooge in the text) *“Give us a kiss!”* |
|  |  |  |
| Recommendations from participants | Cast of characters | FG1:Y: *“I have difficulty remembering who the characters are. In this [Book C] I could remember but in an ordinary novel I have to keep turning back and seeing who they were especially if I have a break.”*S: *Should we have a cast of characters?*FG1:Y: *Yes.* |
|  | Pictures  | FG1:F*:”There were too many pictures. Although the pictures did help my enjoyment of the reading.”*FG1: F: *“What it’s got in this one [Book C] is the energy of Dickens’ writing and the joy and detail of the pictures. And the pictures go with that as well.”*FG1:C: *“The illustrations were lively and in that sense they picked up some of the energy of Dickens’ imagination.”* |
|  | Physical quality of text and paper | FG1:F: *“ The sans serif print in B and the yellow paper and the narrow margins made it difficult.”*FG2:L*: “Yes I’d go for the whiter one too, but that’s for me.”*FG1:C*:”I like the serif (in Book A) because it leads you on.”*FG1: Y*:”I liked the large print. Otherwise I’ve got to wear glasses.”* |
|  | Quantity of text on page | FG1/2:R: *“ In this book (B) there’s so much writing, it could be daunting.”*G: *“So what do you think about the amount of text and pictures in Book C?”*FG2:M: *“Good.”*FG2:L: *“Yes, they’re fine, and there’s not too many words on a page.”* |

*Theme 1. General reading attitudes*

General interest in reading, reading habits in families, interest in book groups

All participants were keen readers, but several of them had not been encouraged to read much in childhood. The view of reading as an escape and a comfort was expressed, and also something which one did in peace and quiet. The idea of a book group was welcomed by several participants.

*Recall*

All participants from FG1 could recall reading at least parts of each of the three versions of *A Christmas Carol*. FG2:M and FG2:N were unable to recall previously viewing the books, even though their carers confirmed that they had been provided these books to read over the previous two weeks. Nonetheless, they participated fully in the focus group, contributing to spirited discussion. FG2: L recognised book C (our adaptation) once she was shown an illustration of Scrooge’s door knocker turned into Marley.

*Liveliness of discussion*

Both discussions were lively and actively involved all participants. FG1:C spoke 50 times; FG1:F 38 times; FG1:Y 32 times; and FG1/2:R 29 times. FG2:Lspoke 50 times; FG2:M 49 times; FG2:N 7 times and FG1/2:R 2 times. Mean interjection in discussion was 32.125 times. The reduced contribution of FG1/2:R to the second group may have been from fatigue and concentration loss, as he said that he was very tired and was looking forward to returning home.

*Theme 2. Preference for the original Dickens*

*Oversimplifying ‘loses the voice of Dickens’*

Version C was ‘too simple. It lost Dickens.’ FG1:1 comparing C to ‘the rich imagery’ used in the original.

*Enjoyment of original text*

The original imagery (FG1:1) triggered memories of Scrooge, and provoked a strong, humorous and emotional response, particularly in Focus Group 2.

*Language play generated*

Participants appreciated and utilised Dickens’ rich language. When Focus Group 2 ate snacks during the discussion, they engaged in lively play on words from the text, relating to the word covetous, and to some Thanksgiving turkey, provided by the author SR. The reading seemed to evoke stimulating discussion between the participants.

*Theme 3. Recommendations from participants*

The participants advocated for changes that would make the adaptations more readable for PLWD. While they agreed that retaining the original “detail and rhythm” (FG1:C) of Dickens’ language was important, the participants made further recommendations about physical characteristics of the book. These included using a cast of characters, appropriate illustrations avoiding childish pictures (FG1:C: ‘At the risk of being dismissive, childish.’), using white paper, with large serif font; and judicious shortening of the story, while retaining the original style of the author.

### *Discussion*

The feasibility study tested the practicality of creating and trialling an adapted book which was appropriate to the tastes and needs of two groups of people living with dementia. It had no particular hypothesis, although the researchers hoped that the participants would enjoy the process, but it was intended to investigate the participants’ reactions to reading in general, participating in a book group and their opinions on Book C. The liveliness of the discussions in both Focus Groups, and the enthusiasm for setting up books groups supported the idea that shared book reading in book groups would be popular, beneficial and clearly very stimulating. The participants were articulate in their likes and dislikes regarding the style and content (preference for original Dickens), and the format of the books. They all demonstrated enjoyment in the excerpts from Book B, the original Dickens, under discussion, and even generated their own word play triggered by these excerpts. In other words, when they read from Book B, although they were ‘reading in the moment’, and not necessarily appreciating the concepts and overall context of the story, they understood the characterisation, and they found pleasure in the language.

Because of the paucity of literature around the topic, the writing of adaptation Book C was guided by general advice on writing for ‘aphasia-friendly’ health literature for stroke patients, suggesting that the syntax and vocabulary should be simplified, and that the font should be around 16 points, the paper colour and text should be clearly contrasting, ie black and white, and possibly that the font should be sans serif, as it was judged to be easier on the eye. Illustrations were considered important. It was certainly true that our participants appreciated the large font and clear contrast, but they seemed to like serif better than sans serif, as the letters were easier to distinguish. Some liked the relative sparsity of words on the page, but some thought we had over done it.

 A number of people said they liked the pictures, but that there were too many of them, which may suggest that they felt an excess of illustrations was infantilizing. But the clearest message which came through the focus groups was that the participants really enjoyed the richness of Dickens’ language, even if they could not always remember the context in which it occurred. They did not appreciate the simplification of the language in Book C, and they did not really enjoy the child-focused language in Book A. Even the participants in Focus Group 2, in the dementia unit of an RACF, were able to discuss passages read from each version of the CC with impressive articulation.

### *Limitations*

As has been suggested above, there are difficulties obtaining reliable information from the population under investigation in this study, because of their cognitive limitations. It was therefore impossible to find quantitative data around what they had read, so our data was confined to the information gained from the focus groups.

### *Conclusion*

What was striking in this feasibility study was the command and appreciation of language, even if the context was not always grasped. The engagement with the original Dickens was especially salient, because initially we had thought that the language would need to be simplified. But the language in itself was not a problem. It was the ‘keeping track of the characters’, and, by analogy, the plot, that was at issue. Simplification was not always appreciated, and was sometimes seen as infantilising.

Great energy was generated in the focus group discussions, which can be seen in the energy of the word play reported in Table 2. The participants enjoyed talking about the excerpts from the books discussed during the focus groups, even if they could not recall reading them previously.

As a result, the researchers have concluded that in this limited study, shared book reading, operationalised through book groups, can increase enjoyment of life, and can stimulate language production. They also believe that adaptations of texts are necessary to make reading enjoyable for people living with dementia, but the model should be shortened versions of original texts, with clear markers to indicate characters, some appropriate illustrations, and large print. Each double-page spread should be designed to be a stand-alone reading experience, while maintaining the integrity of the whole.

## Step 2: The Pilot RCT plus qualitative evaluation

### Introduction

The main purpose of the pilot RCT was two-fold: First, to test the practicability of conducting a full RCT in this population to examine whether, or not, participation in a dementia-friendly book group enhances the quality of life of people with dementia living within an RACF, compared to participation in activities as usual at the RACF. The 15-item Resident QoL-AD-self and proxy report was the primary outcome measure of interest in this research, and the pilot RCT, based on 18 to 20 dyads of participants living with dementia (PLWD) and carer participants, provided data to enable us to design a well powered full RCT focussed around this outcome. Participation in a book group, as a literary arts intervention, may also enhance the level of thriving within the institution of the RACF, and improve theory of mind, mood, cognition, and behaviour in people living with dementia. These were measured using the battery of assessments described below. The feasibility of using this battery of tests on PLWD was carefully assessed, as was the scheduling of the book group intervention (twice weekly for seven weeks) with the RACF facilitators. The resourcing of time and energy for participants, blinded assessors, and book group facilitators was evaluated in this pilot study.

Secondly, the audio-recorded data from the book groups in this study were transcribed by Dr Claridge and Dr Kappagoda, and coded thematically by Drs Claridge, Kappagoda and an independent linguistic specialist, using methodology as outlined below. With a sampling of 9 to 10 participants with differing levels of strengths, interests, and disabilities, divergent and convergent narratives were explored for analysis, to enrich understanding of the lived experience of the person with dementia whilst participating in a facilitated book group at the RACF. Linguistic analysis on the transcribed data, using D-level scales and proportional density analysis, was also carried out to evaluate the language effect of book group participation. Dr Kappagoda also conducted qualitative analysis of intra- and interclausal meaning relationships. This analysis is currently being undertaken and results are pending.

The book groups were semi-structured group meetings, facilitated by a trained diversional or activity therapist at the RACF, using a step-by-step facilitator's manual written by the investigators to enhance the fidelity of the intervention. The reading materials include the series of dementia-friendly books based on classic literature (see [www.dovetalepress.com](http://www.dovetalepress.com)) designed and produced by Dr Rimkeit and Dr Claridge. The facilitator’s manual provided instruction on how to run the twice weekly book groups for seven weeks using the following titles: *A Dovetale Press Adaptation: A Christmas Carol Charles Dickens, Little Women Louisa May Alcott, Sherlock Holmes The Adventure of the Blue Carbuncle, The Garden Party & The Doll’s House Katherine Mansfield*; and *A Dovetale Press Selection: Poetry for the Restless Heart.* The books were adapted to enhance enjoyment and accessibility for the person with dementia and include evocative illustrations for stimulating book group discussion. The facilitator’s manual encouraged the participants to share personal views and opinions, rather than relying on semantic knowledge or memory, which may now be out of reach because of cognitive decline. The book groups were designed to be strengths-based for people with dementia, many of whom, we anticipate, could still enjoy sharing a 'good read', with all its psychosocial and cognitive benefits.

### Study Aims for the Pilot RCT

The key purposes of the pilot RCT were:

1. To assess the feasibility and utility of the assessment measures and processes to ascertain how burdensome the assessment process is for participants, family, clinical assessors, and facilitators. The pilot study answered the questions: Can the proposed patient population handle the burden of two full assessments as described below? If not, which parts of the assessments should be excluded from the full study?
2. To assess the size of any effect of the intervention on Quality of Life (using Resident QoL-AD-self and proxy) in our pilot population, by comparing QoL-AD pre- and post- intervention. Since the pilot included only 18 to 20 dyads (of participants with dementia and carer participants), allocated to intervention and control arms, we did not have sufficient power to determine statistical significance. However, we anticipate that on analysing the data from the pilot (still pending at the time of this protocol draft) the pilot study will provide helpful information about the possible size and variability of any change in Quality of Life due to the intervention.
3. To provide sufficient data for the qualitative linguistic analysis.

This analysis used Interpretative Phenomenological Analysis to explore the lived

experience of a convenience sampling of participants in the book groups; and will

compare change in language with D-level scale and proportional density analysis,

from a convenience sampling of participants, from the first to the last session of

the book group intervention. Qualitative analysis of intra- and interclausal meaning

relationships will also be carried out.

Participant Characteristics and Sample Size:

To achieve the aims of the pilot RCT, 20 dyads of PLWD and their Carer-participants were selected from two Bupa Care Homes in the lower North Island of New Zealand. Each Care Home had 10 participant-dyads – 5 randomised to the book group, and 5 randomised to “usual care.” Our original design recommended that one RACF enrol participants with mild to moderate dementia (rest home or hospital level care) and the other RACF enrol participants with moderate to severe dementia. However, in practice, this became too cumbersome for the RACF staff and what ended up happening was that at each of the two RACFs the book groups contained a mixture of participants with all stages of dementia. Several participants with mild to moderate dementia complained that some of the participants were too confused to join into the discussions and at times were distracting for the participants with less severe dementia. In assessing this issue, we concluded that for the full RCT (step 3) we would limit the participants to those PLWD with mild to moderate disease, as assessed by the Addenbrooke’s – III by the research clinician. We would include those with ACE-III scores of between 36 and 82 (35 and below representing severe dementia and 82 representing the cut off for 100% reliability for a diagnosis of dementia) (Driving with Dementia Working Group Auckland, Counties Manukau, Waitemata and Northland DHBs, 2014) (Callow, Alpass, Leathem, & Stephens, 2015). A goal would be to later conduct a separate study, possibly a qualitative one at the RACF secure dementia unit, to assess a modified book group for PLWD of severe stage.

Assessing the burdens/ resource requirements:

The participants were required to meet with the blinded assessor in an initial interview at baseline and a week after completion of the seven-week trial. The assessment process, measuring Resident QoL-AD self-report, Thriving of Older Persons Assessment Scale (TOPAS), Faces Test for Theory of Mind, Addenbrookes’-III cognitive assessment, and the Geriatric Depression Scale Short Form (GDS –SF), took approximately 1 hour. For the pilot, we considered whether this assessment process was too burdensome for the participants and whether it causes undue anxiety. We found that it did not, although for some participants, the total assessment was conducted over two or even three sessions, depending on the severity of dementia of the participant, with more severe dementia taking more sessions to complete the battery. We did not extend any one assessment session for longer than one hour to reduce strain on the PLWD. In addition, we considered resource obligations for the blinded assessment, which was undertaken as a Scholarly Project by a Psychiatric Registrar (Dr Kappagoda), supervised by psychogeriatrician and clinical investigator Dr Sally Rimkeit, and independently by Dr Rimkeit. We found that one assessor could assess all 10 Participants in one RACF over a period of 3 – 4 days to one week. This required that the staff in the RACF were able to identify the eligible participants. At one RACF Dr Rimkeit consented all participants; in the other the RACF senior staff (registered nurses) conducted the informed consent process. Through the pilot RCT, we also evaluated whether blinded assessment was practical or achievable. In all but one case, the assessors did not know which intervention (book group or usual activities) the participant had received (in one case, the participant told the assessor). Importantly, the pilot study allowed opportunity for review and feedback from our sponsor Bupa Care, who is providing staff resourcing for recruitment and facilitation of the book group intervention. Beth McDougall is the Dementia Care Advisor for Bupa and has agreed to work with facilities closely during the study to address any clinical issues that arise. Initial discussions with Ms McDougall and staff at the Bupa Homes who conducted the Pilot study were that, with good management, the interventions can be easily carried out within the normal activities of the Care Home and that a twice weekly book group was inherently feasible, if incorporated into the activity schedule of the RACF. What was more onerous for the RACF staff was carrying out the consenting process and it was agreed that for the multicentre full RCT, the research clinicians would be responsible for the consenting of potential participants.

As anticipated for the full RCT, for the pilot study, we required the recording of demographic factors on each participant, including, by proxy report, age, gender, marital status, nationality, ethnicity, Iwi if Maori, placement level in RACF (rest home, hospital or secure dementia unit), years of education, and estimated number of books read each year 10 years ago. Although we will not use these variables for the analysis of the pilot study, we collected them so that we can describe our participants, and trial our data collection mechanisms.

The pilot study data is currently being analysed.

Assessing Effect Size and Variance: We anticipate that the pilot RCT will provide data for refining protocol requirements for the full project. This includes estimates of mean and variance of the effect size, from which a sample size estimate can be made. The required sample size will be calculated for the primary outcome (Quality of Life), but the power available to test secondary outcomes will also be calculated.

The assessment tools for the pilot RCT, and proposed for the full RCT, are:

1. Primary Assessment: The change in Quality of Life, as measured by the Resident QoL-AD-self and the Resident QoL-AD-proxy reports
2. Secondary Assessments:
3. Change in “Thriving” (TOPAS self-report and TOPAS-proxy );
4. Change in Theory of Mind ability (Faces Test Theory of Mind);
5. Change in Cognitive functioning (Addenbrookes’ Cognitive examination, version III);
6. Change in mood (Geriatric Depression Scale-Short Form);
7. Change in behaviour (Neuropsychiatric Inventory);

Qualitative Analysis: The Pilot study also enabled us to complete the Qualitative evaluation of the book group experience, namely:

1. To use Interpretative Phenomenological Analysis to explore the lived experience of a convenience sampling of participants in the book groups;
2. To compare change in language with D-level scale and proportional density analysis, from a convenience sampling of participants, from the first to the last session of the book group intervention. Qualitative analysis of intra- and interclausal meaning relationships will also be carried out.

We are planning on combining the Full RCT project, as below, with another qualitative study to provide a robust mixed-methods project to fully understand the effectiveness and lived experience of attending a dementia-friendly book group. We will be seeking HDEC approval for another qualitative study of the lived experience of participating in a dementia-friendly book group at the public library. Our hypothesis is that the PLWD will experience attending a book group in community as a means of “regaining confidence and identity within their communities and to exercise their choice to do things and develop relationships that give their lives meaning”, as per the Recovery Model (Jacob, 2015).

Step 3: The Full RCT to compare dementia-friendly book groups in the RACF to “usual activities” with respect to Quality of Life, Thriving, Theory of Mind ability, Cognitive Functioning, Mood and Behaviour.

Methods: Selection of assessment tools for the full RCT, assessed for practicability in the Pilot RCT.

*Improvement in quality of life* has been chosen as the core goal of the Book Group Project. Quality of life is defined by the World Health Organisation (WHO) as

“Individuals’ perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, personal beliefs and their relationship to salient features of their environment (WHO, 1997).

Quality of life is one of the primary outcome goals of the clinician working with service users with dementia (Longsdon, Gibbons, McCurry, & Teri, 1999) though this is seldom formally measured in the course of clinical work. We have chosen to use the Resident Quality of Life in Alzheimer’s Disease (Resident QoL-AD) and Resident Quality of Life Proxy in Alzheimer’s Disease (Resident QoL-AD-Proxy) originally designed in 1999 by Logsdon, Gibbons, McCurry and Teri (Longsdon, Gibbons, McCurry, & Teri, 1999) and adapted for RACF residents by Edelman in 2005 (Edelman, Fulton, Kuhn, & Change, 2005). We will use both self and carer proxy reports, as with the Logsdon study, for a composite weighted score, as described below. It has been shown to have acceptable internal consistency and test-retest reliability as well as good construct validity. We hypothesize that the intervention of book group reading twice weekly for 14 weeks, with reading materials adapted from classic stories and poems, will enhance quality of life. As we are pre-selecting residents with dementia that have a level of retained language skills (InterRAI scores of 0 or 1, in Section D Communication and answering informed consent questionnaire with Flesh Reading Ease Formula > 70), we assume valid self-reporting of quality of life. Previous research has consistently found that self-report of quality of life is higher than proxy report and this is predicted in our study findings (Crespo, de Quirós, Gomez, & Hornillos, 2012).

In testing the QoL-AD and QoL-AD-proxy on 77 community-dwelling subjects with AD and their caregivers, the QoL-AD was administered in an interview, with oral responses recorded by the interviewer. The QoL-AD-proxy was completed as a questionnaire, filled out by the caregiver. A weighted composite score was calculated by multiplying the QoL-AD score (13 questions, on a 1 to 4 scale, from poor to excellent, hence 13 to 52 points) by 2, adding the caregiver score, and dividing the sum by 3. Only 5 patients with MMSEs of under 10 were unable to complete the measure. Persons with dementia and caregivers achieved good agreement on items rating mood, energy, physical health, and self, but lower agreement on memory and ability to do chores. Brighter mood (using the Hamilton Depression Rating Scale) and higher Pleasant Event Scale-AD scores correlated most closely with quality of life weighted composite scores. MMSE and functional scales (including Activities of Daily Living and Instrumental Activities of Daily Living) did not significantly predict quality of life scores. Interestingly, the only demographic variable shown to have predictive value after linear regression analyses were patient and caregiver education levels (Longsdon, Gibbons, McCurry, & Teri, 1999).

QoL-AD was used in Aimee Spector’s 2003 CST study for community-dwelling subjects. Edelman (Edelman, Fulton, Kuhn, & Change, 2005) have produced a modified Resident QoL-AD to better reflect life while living in an RACF, removing marriage and finance and replacing instead with questions about people who work there, ability to take care of oneself, ability to live with others, and ability to make choices in one’s life. The original item ‘ability to do chores’ was changed to ‘ability to keep busy’, with several other minor changes. The adapted 15-item scale was rated by residents and by proxy carers, using the original 4-point scale (poor, fair, good, excellent). Internal consistency of the adapted scale was adequate. A 2017 systematic review identified 16 good quality studies on RACF resident quality of life (Robertson, et al., 2017). Most of the studies used the QoL-AD-proxy scale with some using the Resident Version. They found good interrater reliability between the proxy-raters, and as with previous analyses, the self-ratings were higher in general than the proxy ratings. (Crespo, de Quirós, Gomez, & Hornillos, 2012). The 15-item Resident QoL-AD self-rating and proxy-rating will be used in the Book Group Project, as all of our book-groups take place at the RACF and all participants are resident there. The study has been powered using the 2003 CST results of Amiee Spector (Spector, et al., 2003).

As the multicentre RCT takes place at the RACF with residents at the facility, one of the secondary measures in our study is *‘thriving’, or how well the individual has adjusted to life at the RACF*. The Thriving of Older People Assessment Scale (TOPAS) self- and proxy-ratings has been designed by Bergland et. al, with satisfactory internal consistency and construct validity (Bergland, Kirkevold, Sandman, Hofoss, & Edvardsson, 2014), to specifically focus “on well-being in relation to how the person has adjusted to the institutional context”(Bjork, et al., 2017). It is a lengthy 32-item questionnaire and is designed for the older person, not for people living with dementia. The authors suggest that TOPAS would benefit from further testing in other populations and contexts. We have communicated with one of the authors, Prof Edvardsson at La Trobe University in Melbourne Australia. They will require us to use the full 32-item questionnaire in our sample. The pilot study will reveal whether or not this places too much of a burden on our participants.

*Theory of Mind*, as described above, is thought to improve through regular book reading as outlined above. It is also thought to deteriorate in Alzheimer’s disease, for reasons not yet fully understood. Fliss et al (Fliss, et al., 2016) explored this in their 2016 study of 42 Alzheimer’s patients and 23 healthy controls using an adapted version of the Reading the Mind in the Eyes Test (Baron Cohen, Leslie, & Frith, 1985) which they called The Eyes/Faces Test (EFT) (Fliss, et al., 2016). This is a simplified test to measure emotion recognition and affective Theory of Mind in people with dementia. While no significant difference was found between EFT scores between dementia and control groups, there was a correlation between EFT scores and educational level and Frontal Assessment Battery (primarily assessing executive functions). A previous study by Laisney (Laisney, et al., 2013), using the unrevised Reading the Mind in the Eyes Test, they found a statistical difference between participants with dementia and controls, with controls showing higher Eyes Test scores than people with dementia. In the Book Group Study, Theory of Mind testing is a secondary outcome measure and using the full 36-item test, with four choices for each picture, lengthens the battery of testing unsatisfactorily. Hence, we have elected to use the Faces Test from 1997 (Baron-Cohen, Wheelwright, & Jolliffe, 1997) which consists of 20 faces with two choices of emotional expression.

Assessment of *cognitive function* will be accomplished using the Addenbrookes’ Cognitive Examination – version III (ACE-III). The original ACE was developed in 2000 and revised in 2006 as an improvement to the Mini Mental State examination (MMSE). It assesses several cognitive domains: attention/ orientation, memory, verbal fluency, language and visual-spatial functioning. The MMSE is included in the test, and the ACE-R has been modified for the New Zealand context. Normative data for the ‘kiwi’ ACE-R gave acceptable internal consistency (Cronbach’s alpha = 0.70), good concurrent validity when compared to other tests, and good test-retest reliability. Norms have been developed by age group, education, ethnicity and sex. Because the MMSE is now strictly under copyright, the Addenbrooke’s revised version has been withdrawn and the Addenbrooke’s III (ACE-III) has replaced this, with adequate sensitivity and specificity, with similar validity and test-retest reliability compared to ACE-R (Noone, 2015). ACE-III has been adapted to use in New Zealand and Australia. Because all participants in the study (see inclusion criteria below) will have expressed an interest in reading and joining a book group, we may be pre-selecting people who have higher cognitive reserve, and hence possibly a more rapid cognitive decline (Stern, 2012). However, because the full study will be powered adequately, randomised and the assessments blinded, we hope to avoid this problem.

*Depression symptoms* have been closely correlated with quality of life measures (Longsdon, Gibbons, McCurry, & Teri, 1999). To reduce the burden of lengthy assessment pre- and post- trial for the participants, we have elected to use the Geriatric Depression Scale-Short Form (GDS-SF), which is a 15-item questionnaire to screen for depressive symptoms (Yesavage, 1988) (Feher, Larrabee, & Crook, 1992). In his 2012 review, Sheehan suggests that it is sensitive to change and reliable in RACF residents. Although it has shown adequate validity in people with mild dementia, use in people with more severe dementia may be limited due to language comprehension difficulties (Sheehan, 2012). As the Book Group Project selects participants with adequate receptive and expression communication skills, we anticipate that completion rates by our participants will be satisfactory for analysis of change over time in control versus intervention participants.

Neuropsychiatric Inventory (NPI) measures will be used by the carer participant report to detect any *changes in behaviour* associated with the seven-week trial. The NPI has been shown to be a valid, sensitive, and reliable measure of both frequency and severity of a wide range of behavioural symptoms, including agitation, irritability and apathy (J. L. Cummings, Rosenberg-Thompson, Carusi, & Gornbein, 1994) (Sheehan, 2012). The study on shared reading groups by Davis and Billington used the NPI as a primary outcome measure in the quantitative arm of their study. Because scores were extremely low (including many scoring zero) at baseline, the NPI data was not further analysed. We may find the same limitation in its use in the Book Group Project. However, unlike the Davis and Billington study, we are including a group of participants residing in secure dementia units, likely placed there because of challenging neuropsychiatric symptoms. We hypothesise that participation in book groups may provide meaningful activity that reduces challenging behaviours, and the NPI measures may significantly decrease from baseline.

### Methods: Statistical Study design and descriptive analysis

*Sample/participants*

Participants will be recruited at Bupa RACFs throughout New Zealand, and potentially Australia and the United Kingdom (awaiting confirmation from these regions).

*Inclusion Criteria*

1. All participants will have a medical diagnosis of dementia, or for Carer Participation will be a carer for someone diagnosed with dementia. In addition, the Bupa facility staff will attest that, in their latest InterRAI (InterRAI Long-Term Care Facility (LTCF) Assessment Form Version 9.3, copyrighted), the participant with dementia has a recorded diagnosis of Alzheimer’s disease or Dementia other than Alzheimer’s (section I: Disease Diagnosis). Participants will be recruited as a dyad of Carer (family member) and person living with dementia (PLWD).
2. Participants with dementia will be recruited from those living in rest home or hospital level care (with likely mild-moderate dementia) and those living in secure dementia units (likely moderate - severe dementia). Participants with dementia will reside at the Bupa Care Home. The Carer Participants can reside outside of the Care Home, in community, or at the Bupa Care Home.
3. Participants will be recruited by invitation by the facility manager, or his/her surrogate, with referral to a poster giving information about the book group.
4. All participants with dementia will score 0, 1 or 2 on all parts of Section D: Communication and vision of the InterRAI Long-Term Care Facility (LTCF) Assessment Form Version 9.3, copyrighted.
5. All participants with dementia will be recorded as NOT having any problems with verbal abuse, physical abuse or socially disruptive behaviour in their InterRAI (Section E.3, parts b, c, and d)
6. “With patient autonomy being a guiding principle in health care law, it is important that the test that sets the limit for capacity is at a level that allows most people to make their own decisions about treatment”. (Gunn, 1994)) . In consultation with HDEC, we have carefully designed our consent process to respect this autonomy principle. As per **The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996, a**ll participants will be deemed to have the **capacity** to give informed, written consent (even if they have been deemed incompetent within PPPR legislation). This written consent will be sought only after they have had time to fully read the Participant Information Sheet (PIS) and Consent Form, speak to family members (who have been provided with a Family Information Sheet and Carer Views on their Relative’s Participation in the study), and had an interview with the clinical researchers (Drs Rimkeit or other research clinician), so that their questions about the study are fully answered. In this consent process, we will ensure that those who agree to participate do so because 1) it is their personal, informed choice to participate, and 2) they believe it is in their best interest to participate.
7. The carer-participant for each PLWD will receive their own letter of information for the role they will play in the study and interview with the researchers and will sign their own consent form.
8. Participants with dementia will score between 36 and 82/100 on the Addenbrooke’s – III, as tested by the research clinician.

*Exclusion Criteria*

1. Potential participants with comorbidities which would preclude them from participating in the book group for seven weeks will be excluded; this will be assessed by the facility manager or his/her surrogate.
2. Potential participants who score 3 or 4 on any parts of Section D: Communication and vision of the InterRAI Long-Term Care Facility (LTCF) Assessment Form Version 9.1, copyrighted will be excluded from the trial.
3. All potential participants with dementia who are recorded as exhibiting any verbal abuse, physical abuse or socially disruptive behaviour in their InterRAI (Section E.3, parts b, c, or d) will be excluded from the study.
4. Participants who score 35/100 or less on the Addrenbrooke’s – III will be excluded from the RCT.

### *Ethics Approval*

Ethics approval will be sought through the Health and Disability Ethics Committee. The Pilot RCT, with similar protocol as the Full RCT received HDEC approval on 31 August, 2017 (ref 17/NTA/133: *Reading for Pleasure: The benefits of a dementia­friendly book group).*

*Informed Consent Procedures*

The manager of the Bupa facility must provide written agreement for the facility to take part in the study. This study seeks participants through Bupa (study sponsor) Residential Aged Care Facilities who have been medically diagnosed with dementia and their Carers, as a PLWD-Carer dyad. For those people expressing interest through the recruitment poster at Bupa, the manager will send out the information sheets, and the consent forms.

A clinician from the research team will carry out the consenting process for the PLWD. They will meet face-to-face with the PLWD at the RACF. If the person wishes for a support person, Carer or family member to be present during this consenting interview, then this will be arranged by the research team. “With patient autonomy being a guiding principle in health care law, it is important that the test that sets the limit for capacity is at a level that allows most people to make their own decisions about treatment”. (Gunn, 1994)) . In consultation with HDEC, we have carefully designed our consent process to respect this autonomy principle. As per **The HDC Code of Health and Disability Services Consumers' Rights Regulation 1996, a**ll participants will be deemed to have the capacity to give informed, written consent (even if they have been deemed incompetent within PPPR legislation). This written consent will be sought only after they have had time to fully read the Information Sheet, speak to family members (who have been provided with a Family Information Sheet and Carer Views on their Relative’s Participation in the study), and had a face to face interview with the clinical researchers so that their questions about the study can be fully answered. In this consent process, we will ensure that those who agree to participate do so because 1) it is their personal, informed choice to participate and 2) they believe it is in their best interest to participate.

The Carer-Participant for each PLWD will receive their own letter of information for the role they will play in the study and interview with the researchers and will sign their own consent form. This will be done through phone conversation, and mail or emailing of the consent form back to the research team.

Participants will understand they can leave the trial at any time. If they are allocated to the control group, they will be able to take part in a book group after the study finishes.

The goal is to recruit two hundred sixty participants with dementia, with their Carer Participant, from 26 RACFs in New Zealand, Australia and the UK (14 in NZ, 6 in Australia and 6 in the UK). Of these participants with dementia, half will be randomised to receive the intervention, and half will receive standard usual care for that facility. Only those randomised to the intervention will have access to the study books and will be able to attend the twice-weekly book groups. The study intervention consists of book-reading and twice weekly dementia-friendly book groups for a period of seven weeks.

If a Bupa Care Home has had a book group as part of their usual activities, then there will be a ‘wash out period’ of 8 weeks, with no book groups at the Care Home being conducted before the RCT commences, or alternatively, Bupa Care Homes will be chosen that have not had book groups as part of their usual activity.

Once all participants at a given facility have provided written, informed consent, randomisation will be done from the central Data Office (Dr Dalice Sim, University of Otago).

*Registration and randomization of patients*

Bupa facilities with sufficient potential participants to be able to take part in the study will be recruited into the study (a minimum of 10 participants per facility is required). Within those facilities, residents who express an interest in participating (responding to poster advertisements and invitations from staff) and who meet the eligibility criteria will be invited to consent to the study. Once the consent process has been finalised (as detailed above), demographic information will be collected on each participant with dementia. Baseline measure of quality of life using Resident QoL-AD self-report and proxy- will be collected. Other secondary measures, TOPAS, EFT, ACE-III, GDS-SF, and NPI, will also be collected at baseline, or pre-intervention for both intervention and control participants. These assessments will be carried out by clinical members of the research team (Drs Rimkeit and a Psychiatric Registrar under Dr Rimkeit’s supervision). If the ACE-III score is above 82 or below 36 at pre-assessment, the participant will be excluded from the RCT, but will be told that they can participate in a book group if they wish, after the study is finalised.

Within each facility, blocked randomization will be used to ensure approximately equal numbers of patients from each facility are in the intervention and control groups. Residents and staff cannot, because of the nature of the intervention, be blinded to intervention assignment. However, all assessments (including the baseline assessment) will be conducted by a qualified clinician blinded to the treatment assignment.

Post-trial assessments will be completed by a qualified clinician blinded, as possible, to the treatment assignment. There is a realistic understanding that blinding may be unmasked when working with people with cognitive impairment, perhaps forgetting that the assessor should not know whether or not they joined the book groups or activities as usual at the RACF. The carer assessments pre- and post- intervention will not be blinded to which arm of the study the participant was in; this is an accepted limitation of the study.

All residents who consent to participate will be registered with the central Data Office (Otago University). All data collected will be managed by the central Data Office at University of Otago.

*Size of study*

The primary outcome for each patient is the change in score on the Resident QoL-AD from baseline to post-intervention. Spector et al (2003), using a similar design to investigate cognitive stimulation therapy, observed an increase of 1.3 + 5.1 (mean + standard deviation) in the intervention group, and a decrease of 0.8 + 5.6 in the control group over the same period of time. A total sample size of 216 patients (108/ group) is sufficient to provide 80% power to detect this size of difference at the 0.05 level. Spector et al (2003) experienced a withdrawal rate of approximately 20% in their study, and so we will recruit a total of 260 patients (130/ group) to provide enough fully evaluable patients for our study. We anticipate a total of 26 institutions will provide sufficient participants for this study (14 New Zealand, 6 Australian and 6 in the UK).

The goal is to recruit 10 patients at each clinical site. Of these, five will be randomised to receive the intervention, and five will receive standard usual care for that facility. Only those randomised to the intervention will have access to the study books and will be able to attend the twice-weekly book groups. The study intervention consists of book-reading and twice weekly dementia-friendly book groups for a period of seven weeks.

### *Monitoring of trial progress:*

Each facility which commits to participation will be registered with the Data Management Centre (DMC, University of Otago, Wellington, New Zealand).

At patient randomisation, all patients will be registered with the DMC. Accrual will be assessed at least monthly. Baseline data will be sent to the DMC at initiation of the intervention, checked and entered into the data base. Eligibility criteria will be checked.

Any withdrawals will be notified to the DMC (including withdrawal of control patients).

Post intervention data will be returned to the DMC in a timely manner, checked and entered.

### *Forms and data handling*

When recruiting for each facility is completed, consent forms will be verified and randomisation will proceed under the direction of the DMC. Baseline data will be collected and entered. Post intervention data will be collected at week 9 and entered into the data base. The data forms will be kept in a locked filing cabinet, identified only by study number. The code for identifying the participants and their support person will be kept in a password-protected file, and the data files will also be password protected. Only the named investigators of the study will have access to the study documents and files. All study data will be kept for 10 years and then destroyed.

### *Protocol deviations*

Facilitators will be asked to record patient’s attendance at the book groups. Any patient who “drops out” for any reason (death, move from facility, declines to participate) will be so noted and, if possible the reason recorded. For the full RCT, the principal analysis will be intention-to-treat (including all patients in their treatment groups regardless of level of participation), although as per protocol analysis will also be done.

### *Plans for statistical analysis of the full RCT*

All analyses will be done on an Intention-to-Treat basis. Intervention and control groups will be compared at baseline (using t tests or chi-squared tests as appropriate). Initial checks will determine whether or not the Resident QoL-AD is normally distributed. If so (this was true for the CST study), ANCOVA (Analysis of Covariance) will be used to test whether the change in Resident QoL-AD was different between the intervention and control groups, adjusting for baseline characteristics (QoL-AD, TOPAS, EFT, Addenbrooke’s - III, GDS-SF, and NPI.

Secondary analyses, comparing changes in Theory of Mind, Thriving, Mood or Behaviour, using the assessments given above (and used in the pilot study), will use the same statistical method.

 Study Programme

In week 1, all patients (intervention and control) will receive the baseline evaluation, and the intervention will begin. The Assessor will be blinded to treatment allocation, and will be either a Psychiatry Registrar or a Psychiatrist.

During weeks 2 – 8, facility staff will conduct the book groups, and patient carers will provide support to the patients to encourage them to read the books between meetings, attend and participate in the book groups.

In week 9, the final assessment, a repeat of the baseline assessment, will be done, again by a blinded assessor who is either a Psychiatrist or a Psychiatry Registrar.

### Table 1. Study Programme

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Week | Assessors(blinded) | Facilitators | Carers | ParticipantsReceiving intervention | Control participants (C/P) |
| 1 | Administer to participant:Resident QoL-ADTOPAS-ADFaces ToMACE-IIIGDS-SF | Give “A Christmas Carol“ to each Intervention patient (I/P) | Complete:QoL-AD-proxyTOPAS-proxyNPISupport I/P to attend book group, but does not attend.Usual care for C/P | Complete:Resident QoL-ADTOPAS-ADFaces ToMACE-IIIGDS-SFRead “A Christmas Carol” before Book Groups. | Complete:Resident QoL-ADTOPAS-ADFaces ToMACE-IIIGDS-SF |
| 2 |  | Facilitate Book group sessions 1&2: “A Christmas Carol.”Give “Sherlock Holmes” at end of sessions. | Support I/P to attend book group, but does not attend.Usual care for C/P | Attend book groupRead “Sherlock Holmes” before next book groups. | Attend activities as usual at RACF |
| 3 |  | Facilitate Book group sessions 3&4: “Sherlock Holmes.”Give “Poetry Book: Poems of laughter.” at end of sessions | Support I/P to attend book group, but does not attend.Usual care for C/P | Attend book groupRead “Poems of Laughter” before next book groups. | Attend activities as usual at RACF |
| 4 |  | Facilitate Book group sessions 5&6: “Poems of laughter.”Give “Katherine Mansfield: The Doll’s House.” at end of sessions | Support I/P to attend book group, but does not attend.Usual care for C/P | Attend book groupRead “The Doll’s House” before next book group | Attend activities as usual at RACF |
| 5 |  | Facilitate Book group sessions 7&8: “Katherine Mansfield: The Doll’s House.”Give “Poetry Book: Poems of Nature.” at end of sessions | Support I/P to attend book group, but does not attend.Usual care for C/P | Attend book groupRead “Poetry Book: Poems of Nature” before next book group | Attend activities as usual at RACF |
| 6 |  | Facilitate Book group sessions 9&10: “Poems of Nature.”Give “Katherine Mansfield: The Garden Party.” at end of sessions | Support I/P to attend book group, but does not attend.Usual care for C/P | Attend book groupRead “The Garden Party” before next book group | Attend activities as usual at RACF |
| 7 |  | Facilitate Book group sessions 11&12: “The Garden Party.”Give “Little Women.” at end of sessions | Support I/P to attend book group, but does not attend.Usual care for C/P | Attend book groupRead “Little Women” before next book group | Attend activities as usual at RACF |
| 8 |  | Facilitate Book group sessions 13&14: “Little Women.”Thank participants and remind them of the assessments next week | Support I/P to attend book group, but does not attend.Usual care for C/P | Attend book group | Attend activities as usual at RACF |
| 9 | Administer to participant:Resident QoL-ADTOPAS-ADFaces ToMACE-IIIGDS-SF |  | Complete:QoL-AD-proxyTOPAS-proxyNPI | Complete:Resident QoL-ADTOPAS-ADFaces ToMACE-IIIGDS-SF | Complete: Resident QoL-ADTOPAS-ADFaces ToMACE-IIIGDS-SF |

### Monitoring of Potential Risks to Participants

The study protocol is designed to minimise risks to the participants, especially the participants with dementia. Nevertheless, there is some potential for risk or harm to the participants, in particular the risk of becoming anxious or distressed during the process of the study.

Recruitment Process: Potential participants will be invited to be in the study through a Recruitment Poster at the Bupa RACF. There will be an announcement using Recruitment Poster through Beth McDougall, Dementia Care Advisor to Bupa NZ, and/or Bupa RACF Manager at a resident gathering (eg one of their Happy Hours). Interested parties will be provided a Participant Information Sheet (see attached, separate PIS Sheets for PLWD and Carer participant).

The randomisation process necessarily results in some participants not receiving the book group intervention during the course of the study. However, the participants will be informed, and Bupa is committed to offering the book group to any control participant once the study is completed, after the final assessment, so that no participant will “miss out.”

The assessments will also be conducted by Drs Rimkeit or other research clinician. If the assessment process appears to cause distress or exhaustion, they are expert in picking this up early to mitigate harm, eg aborting assessment and offering a later session. The PLWD's usual GP and nurse will be informed, with consent from the PLWD, that the PLWD is in the study. Limits of confidentiality will be explained in the PIS. If an assessment leads to disclosure of a serious disorder, such as depression, or concerns about the experience at the RACF, possibly related to safety, then the assessors Drs Rimkeit or other research clinician will request a meeting with the PLWD, carer, legal personal representative if applicable, and GP to determine appropriate case by case action.

The book groups are designed to minimise frustration for the reader with dementia (see facilitator’s manual) and this activity is unlikely to cause more emotional or physical harm than activities as usual at the RACF. Beth McDougall, Dementia Care Advisor for Bupa, will train and consult with facilitators to pick up changes in behaviour or mood early, analyse causes, and manage distress. She will keep a log of incidents. All incidents will be confidentially logged by Dalice Sim at U of Otago.

It would be unlikely that the intervention will cause any greater harm to PLWD than activities as usual at the RACF. However, if we see that excessive anxiety, agitation, behavioural harm to self or others, or other serious events result from the pilot study, either from the assessment or intervention processes, we will terminate the study for that participant or consider terminating the study altogether. Participants and their family carers will be reminded throughout the study that they can leave the study at any time.

Katalina Sanches, of ACC Main Office confirms if there is an accident during the book group intervention, ACC will provide cover as per usual ACC criteria. As per the request from the HDEC committee, we have added the following statement to the Information Sheets: *“If you were injured in this study, which is unlikely, you would be eligible* ***to apply*** *for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.”*

The other potential harm to the Participants (both carers and participants with dementia) is that their data may be used in a way that does not maintain confidentiality. The inclusion criteria are based on the PLWD’s InterRAI, a standard assessment done in the facility every six months. To ensure confidentiality with these data, only the staff at the Bupa facility will access the InterRAI to determine eligibility (Beth McDougall, Dementia Care Advisor for Bupa, will oversee this process). The investigators will know only that eligibility has been met. On 20 June Review, HDEC committee agreed that although the researchers intend to use the information for a purpose different from why it was collected, the intended research is ethical and appropriate, in the public interest.

 Data collected during the course of the study will be de-identified. Bupa staff will assign consecutive patient numbers to each dyad of PLWD and carer, and no names or other identifying information will be sent to the data centre. All the data will be managed by our data administrator, Dr Dalice Sim, at University of Otago, to maintain strict confidentiality of all participants. All Data will be de­identified, and will be password protected. InterRAI information will only be accessed by Bupa managers, with oversight from Beth McDougall, Dementia Care Advisor, for screening for study participants with dementia.

 All analyses will be reported without mention of the individuals or the staff involved.

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