**Research Protocol**

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| **Title of project** |
| Tailored to me: Evaluating the effectiveness and acceptability of behavioural assessments for people living with dementia |

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| **Project summary.** |
| It is emphasized in the New Zealand Framework for Dementia Care (Ministry of Health, 2013) that people and their care partners should be able to access support for behaviour strategies (including functional analysis; page 39). Despite an increasing body of evidence to show that behavioural principles and technologies can improve the quality of life of people living with dementia, the literature remains limited (Trahan et al., 2011). Additionally, many of the evidence-based assessments used to establish interventions and supports were designed and validated with people with disabilities. As such, there may be aspects of these methods that require adapting for use with people with dementia. For example, Sharp et al. (2023) found that 20% of studies in behavioural gerontology reported difficulties implementing or requiring changes to the method. Assessments may also require adaptation to ensure social validity (i.e., they are acceptable and liked; Wolf, 1978).  This research will focus on two core assessment methods in behaviour analysis; preference assessments used to identify preferred activities, objects, and food, and functional assessments used to identify the contingencies maintaining problematic behaviour. Both have been used to support people with dementia (e.g., Baker et al., 2006; Virués-Ortega et al., 2012), however the aim of this project is to determine how they should be adapted to be effective and acceptable.  Baker, J.  C., Hanley, G.  P., & Mathews, R.  M. (2006). Staff-administered functional analysis and treatment of aggression by an elder with dementia. *Journal of Applied Behavior Analysis, 39*(4), 469–474. <https://doi.org/10.1901/jaba.2006.80-05>  Ministry of Health. (2013). New Zealand Framework for Dementia Care. Wellington: Ministry of Health. <https://www.health.govt.nz/system/files/documents/publications/new-zealand-framework-for-dementia-care-nov13.pdf>  Sharp, R. A., Brand, D., Virués-Ortega, J., & Cowie, S. (2023, in preparation). *Contributions of Applied Behavior Analysis to the Design of Prosthetic Environments for People with Dementia: A Systematic Review*  Trahan, M. A., Kahng, S., Fisher, A. B., & Hausman, N. L. (2011). Behavior-analytic research on dementia in older adults. *Journal of Applied Behavior Analysis, 44*, 687-691. <https://doi.org/10.1901/jaba.2011.44-687>  Virués-Ortega, J., Iwata, B. A., Nogales-González, C., & Frades, B. (2012). Assessment of preference for edible and leisure items in individuals with dementia*. Journal of Applied Behavior Analysis, 45*(4), 839–844. <https://doi.org/10.1901/jaba.2012.45-839>  Wolf, M. M. (1978). Social validity: the case for subjective measurement or how applied behavior analysis is finding its heart 1. *Journal of Applied Behavior Analysis*, *11*(2), 203-214. <https://doi.org/10.1901/jaba.1978.11-203> |

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| **Project details.** |
| The overarching goal is to determine how to ensure that behavioural methods are effective and socially valid to support people with dementia.  ***Study 1.*** *A scoping review of preference assessment methods for use with people with dementia.*  We will systematically explore the literature, extracting data such as diagnosis, abilities, setting, effectiveness, and reported difficulties administering the assessment. This will allow for a synthesis of what is currently known about the use of these assessments.  ***Study 2.*** *An evaluation of the a) effectiveness and b) social validity of preference assessments for use with people with dementia.*  We will recruit and work alongside services, care partners, and people with dementia. For each participant, we will administer the suite of preference assessments (e.g., multiple stimulus without replacement; Raetz et al. 2013, free operant, Roane et al. 1998) to evaluate effectiveness and acceptability.  **Study components:**   * **Survey** (professional care givers and whanau): Professional caregivers and whanau will be given a social validity survey in paper form to fill out before the beginning of the project, after the first preference assessment and after the second preference assessment. The social validity survey will be multiple choice and take approximately 5-10 minutes to complete. * **Phase 1.** Preference assessment (participants living with dementia): During the baseline session, participants with major neurocognitive disorder will participate in a preference assessment used to assess the participants preference of food, objects and activities. This preference assessment may by MSWO or free-operant, depending on the individual participant. The participant will be instructed by the researcher to choose between the options available, and make their preference of the options. Or in the case of the free-operant preference assessment, researchers will be observing the participants interaction with different objects food or activities. The baseline sessions will be approximately 30 minutes, and there will be one to four baseline sessions conducted with each participant (no more than two sessions a day). The baseline conditions will run for approximately 4 weeks. * **Phase 2.** Adapted preference assessment (participants with dementia): We will conduct adapted preference assessments with the participants involved, through cooperation with behaviour analysts, professional carers and whanau through social validity surveys and questionnaires. The participants will undergo another preference assessment, however, this time it is adapted to measure the effect on different indices of happiness and effectiveness of the procedure. The participants will again be given options of preferred items, food or activities, same as in baseline condition, however with the adaptions made to the procedure by the experimenters. These sessions will also be approximately 30 minutes, and there will be one to four adapted preference assessments per participant (no more than two sessions a day). This adapted preference assessment phase will run for approximately 4 weeks. * **Phase 3.** Participants living with dementia will continue to take part in the two preference assessment phases, alternating randomly between the two. Preference assessments will continue to be 30 minute long sessions, one to four sessions per week (no more than two sessions a day). These will run for up to 15 weeks and we will run between 5-15 sessions per participant. This specific design is called an alternating treatments design.   **Methods and measurement**  We will collect direct observation quantitative data on a) preferences, b) indices of happiness as objective measures of enjoyment of the assessment, and c) verbal or physical behaviours that indicate enjoyment or lack of (e.g., smiling, leaving the area). We will obtain qualitative data about the acceptability of each type of preference assessment in interviews, questionnaires, and focus groups with care partners (whanau and professional) and people with dementia. Experimental control will be demonstrated using small-N research designs and we will use visual inspection of graphed data (based on baseline logic; Kazdin & Tuma, 1982). We will recruit between 5 and 10 people diagnosed with dementia, their whānau, and carers.  **Analysis**  Behaviour-analytic approaches will be employed. The majority of the data will be collected by direct observational measurement of behaviours and environmental variables, operationally defined, and collected via pen-and-paper methods (e.g., Johnson & Pennypacker, 2009; Sharp, Mudford, & Elliffe, 2015). Experimental control will be demonstrated with small-N designs, which do not require statistical analyses. In a small-N design, each participant serves as their own control, and is exposed to all conditions. Comparisons of behaviour are made within a participant rather than across participants and we conduct repeated measures of our behaviour of interest (i.e., we measure behaviour throughout each session and phase rather than just pre- and post-intervention). We will use visual inspection of graphed data (based on baseline logic; Kazdin, 1982), a common method of data analysis employed in most of behaviour-analytic research. This involves tracking data visually on graphs, and making data-based decisions during the study. Under this approach, small samples can be highly informative. A key component of small-N design is that we publish our methods in detail (principle of technological). This enables replication; as a field, we are more likely to conduct 20 studies including 5 participants in each rather than one study with 100 participants. This approach allows for a nuanced evaluation of the individual factors that contribute to the effectiveness of an intervention. When working with people with major neurocognitive disorder, a small-N approach is useful because experimental control is unaffected by individual differences in behaviour and the progression of dementia (see Steingrimsdottir & Artnzen, 2015 for a detailed discussion).  **Expected outputs:**   * A dataset demonstrating the adaptations required to ensure that functional and preference assessments are both effective and socially valid for use with people with dementia. * A dataset indicating the common function of behaviour that challenges exhibited by people with dementia (i.e., akin to that reported by Hanley et al., 2003) * Some best practice guidelines to be disseminated within the field of behaviour analysis. * At least three publications in peer-reviewed journals. * At least two conference presentations (behaviour-analytic or dementia). * Connections with local service providers to facilitate further co-designed research, placements for intern psychologists, and employment opportunities for graduates.   **Significance of expected results**  Study 2 will generate data that will be useful for the support of the participants involved. Beyond this impact, our results will also contribute to the growing field of behavioural gerontology. Specifically, we will produce best practice guidelines to support practitioners to expand their clinical practice (aligned with suggestions made by LeBlanc et al., 2012) and contribute to improved quality of life for people with dementia. Although there are a handful of studies using these assessments with people with dementia, the full suite of preference assessments has not yet been evaluated. Our data will contribute to this evidence base. Finally, this project aligns with current focus of the field to ensure the meaningful inclusion of people we support in their care, demonstrating that good behaviour analysis is person-centered and responsive to needs.  Engstrom, E., Mudford, O.  C., & Brand, D. (2015). Replication and extension of a check-in procedure to increase activity engagement among people with severe dementia. *Journal of Applied Behavior Analysis, 48*(2), 460–465. <https://doi.org/10.1002/jaba.195>  Kazdin, A. E., & Tuma, A. H. (1982). *Single-case research designs*.  LeBlanc, L. A., Heinicke, M. R., & Baker, J. C. (2012). Expanding the consumer base for behavior-analytic services: Meeting the needs of consumers in the 21st century. *Behavior Analysis in Practice*, *5*, 4-14. <https://doi.org/10.1007/BF03391813>  Raetz, P.  B., LeBlanc, L.  A., Baker, J.  C., & Hilton, L. C. (2013). Utility of the multiple-stimulus without replacement procedure and stability of preferences of older adults with dementia*. Journal of Applied Behavior Analysis, 46*(4), 765–780. <https://doi.org/10.1002/jaba.88>  Roane, H. S., Vollmer, T. R., Ringdahl, J. E., & Marcus, B. A. (1998). Evaluation of a brief stimulus preference assessment. *Journal of Applied Behavior Analysis*, *31*(4), 605-620. <https://doi.org/10.1901/jaba.1998.31-605>  Sharp, R. A., Lucock, Z. R., & Jones, R. S. (2021). Preliminary investigation of two functional assessment methods for people with dementia: Effectiveness and acceptability. *Behavioral Interventions*, *36*(1), 93-104. <https://doi.org/10.1002/bin.1747> |

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| **Ethics and safety** |
| **Participant distress**  When working with people with dementia / mate wareware, there is the risk of participants feeling levels of distress or discomfort. We have a clear distress protocol to follow. Once we have consent from participants who are going to be taking part in the study, we will ask staff (preferably a staff member and family collaboratively) to complete the Disability Distress Assessment Tool (DisDAT; Regnard et al.,2007) for each participant to outline signs of distress for that participant. They will identify the appearance, vocal signs, habits and the posture of the participant when they are both content and when they are distressed. We expect this should take about 10 minutes to complete. This will be with the research team at all times whilst they are in the care home and available to the staff to ensure that everyone working with the participant is able to recognise signs that they are distressed and be able to react appropriately as soon as any signs appear. If one of the participants in this research were to become distressed, we could presume that the cause may be in or out of our control. If the causal variable is out of our control (e.g., due to other factors such as events in the care home, physical stimuli or internal events such as thoughts), then this would presumably occur whether we were present or not. There will be a staff member present at all times, who will be able to help de-escalate the situation. They will use a calm, gentle, and soft tone of voice, and remove all demands from the immediate environment. They will adopt a non-judgmental and empathetic approach, and offer the person to move to a quiet area. They will also offer a refreshment and ensure that the person is not left alone. We will be aware of body language, physical proximity, and safety. Alternatives to the behaviour in which the person is engaging will be offered, representing a collaborative problem-solving approach.  Once the participant is no longer distressed, we will discuss with the staff, care home manager, whānau, guardian, and participant about whether that participant should continue with the study or not. This judgement will be made in the best interests of the participant as a collaborative decision between those that know the individual the most. If the participant becomes distressed due to something within our control (e.g. they dislike our presence, the procedure or some other factor about the research team/procedure) then the same procedure will be followed as above, with immediately removing our presence from the vicinity and the staff calming the participant. If it is clear we are able to identify the variable that is upsetting the participant, then we can discuss with all involved (as above) whether to continue to not, or whether to modify the procedure to further tailor it to that individual. For example, if there is a specific member of the research team that the participant does not like (for whatever reason; e.g. they have similar features to someone they did not like in their past), then this is easily rectified by removing that person from the procedure for that participant and replacing them with another member. Again, the decision to do this would be made in conjunction with the staff, participant and their whānau if appropriate, and if it was felt that it was in the best interests to withdraw the participant from the study completely then this would be done immediately.  **Informed consent**   1. People with mate wareware will receive the invitation in person from the nominated person in their service. The team will offer to meet potential participants to discuss the study and answer questions. If appropriate, supported decision making will be used. Participants will be asked to provide informed consent after discussion, when it is clear that all questions have been answered. 2. Whānau will receive the invitation and PIS by phone call and in person by the organisation. The team will offer to meet potential participants to discuss the study and answer questions. Whānau will be asked to provide informed consent after discussion, when it is clear that all questions have been answered. 3. Carers / professionals will receive a verbal invitation (via hui) or email invitation (from manager), and the PIS will be provided. The research team will address any questions the professional has and ask for informed consent when it is clear that all questions have been answered.   We have two routes through which a person with dementia may partake:   1. They are able to consent on their own behalf 2. They are able to consent through supported decision making   **Confidentiality**  Pre-existing health data will be accessed from the organisations supporting the people living with dementia only after consent has been obtained from that individual. We will only record demographic information (e.g., age, ethnicity, gender) and medical diagnoses. Data will be de-identified by the researcher at the point of collection (we will assign participants pseudonyms). Collection of data will be limited to that necessary for the specified purposes of the study, or for additional purposes that the participant has explicitly consented to.  De-identified data will carry a participant code or pseudonym (e.g., P1, P2, P3). Because the number of participants is small, a log linking participant code with identifiers is not required. The de-identified data will remain on University of Auckland servers for up to approximately 2 years. De-identified data is stored in zip files long-term by the University of Auckland in in secure cloud-based servers. De-identified data will be retained for 10 years.  Secondary observers collecting inter-observer agreement (a check of data quality in which a second, independent observer is present to collect data; 30% of sessions), and observers collecting procedural integrity (a checklist to ensure the experimenter is following the procedure correctly) will be present during some sessions. They will be required to fill out a confidentiality agreement |

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| **Contributions to knowledge base** |
| Understanding behaviour for people with dementia will directly contribute to developing effective service delivery. The assessments we will evaluate allow for an understanding of how best to ensure that a person can access meaningful activities. Being able to use these assessments effectively, but also in a way valued by people with dementia, will enhance their use, increasing the potential impact for people living with dementia to live well.  Our research is conducted alongside people living with dementia, their care partners, and the services supporting them. We strongly emphasise co-design, and this project will enable a strengthening of the community connections that the Learning and Behaviour Programme has developed. Therefore, this work might have further impact in that it helps to further support collaborations. The inclusion of a Research Assistant provides an opportunity for a promising student or clinician to gain experience in behavioural gerontology, further widening the potential for people with dementia to access behavioural support by contributing to this workforce.  The number of people living with dementia continues to increase (predicted to be 50 million worldwide, with an additional 10 million diagnoses per year; WHO, 2023). The project aligns with the government’s Healthy Ageing Strategy priorities: 5) Implement models of care that are needs based, person-centred and equitable and 6) Support the capacity and capability of the workforce to provide care and support (Healthy Ageing Strategy, 2016). Additionally, it aligns with other action plans and strategies, both in Aotearoa and on the world stage (e.g., Better Later Life – He Oranga Kaumātua, World Health Organisation Global Dementia Action Plan).  Ministry of Health. (2013). New Zealand Framework for Dementia Care. Wellington: Ministry of Health. <https://www.health.govt.nz/system/files/documents/publications/new-zealand-framework-for-dementia-care-nov13.pdf>  Associate Minister of Health. (2016). *Healthy Ageing Strategy*. Wellington: Ministry of Health. <https://www.health.govt.nz/system/files/documents/publications/healthy-ageing-strategy_june_2017.pdf>  Te Tari Kaumātua Office for Seniors. (2019). Better Later Life – He Oranga Kaumātua.  <https://officeforseniors.govt.nz/better-later-life-strategy/>  World Health Organization. (2017). Global action plan on the public health response to dementia 2017–2025. Geneva. Licence: CC BY-NC-SA 3.0 IGO.  <https://www.who.int/publications/i/item/9789241513487> |

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| **Vision Mātauranga** |
| **Indigenous Innovation**  The inclusion of Māori as partners in the research will contribute to the outputs of the project (i.e., best practice guidelines). Including Māori participants will promote the inclusion of Māori knowledge. Because the acceptability of behavioural methods is what is of interest, the project strongly aligns with this theme in the aim to hear the voices of Māori living with dementia and their whānau.  **Hauora/Oranga**  The overarching aim of the project is to improve health and social wellbeing of people with dementia, which aligns with the theme of hauora / oranga. Specifically, we are interested in what makes behavioural methods effective and acceptable at an individual level, which allows for an assessment of how behaviour analysis can meet the distinctive needs of Māori and Māori communities.  **Mātauranga**  We hope to ensure, through the inclusion of key stakeholders and community outreach, that Māori will have a kaitiaki role in the project (i.e., beyond consultation). This will be facilitated by seeking input throughout the project (e.g., implementation, framing of results)  We will ensure the consideration of Māori research design analysis and dissemination of the results in considering Māori ethical framework Te Ara Tika. The project could be categorised as Research Specifically Relevant to Māori (as specified by the MBIE).  <http://www.hrc.govt.nz/sites/default/files/2019-06/Resource%20Library%20PDF%20-%20Te%20Ara%20Tika%20Guidelines%20for%20Maori%20Research%20Ethics_0.pdf> |