# Exploring Pasifika wellbeing: findings from a large cluster randomised controlled trial of a mobile health intervention programme

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## ABSTRACT

**AIM:** The primary objective of this study was to determine the effect of a mobile health (mHealth) intervention on the wellbeing of Pasifika peoples, and to explore factors associated with Pasifika wellbeing.

**METHODS:** The OL@-OR@ mHealth programme was a co-designed smartphone app. Culturally relevant data was collected to examine holistic health and wellbeing status, at baseline, and at 12 weeks (end of the trial). The concept of wellbeing was examined as part of a two-arm, cluster randomised trial, using only the Pasifika data: 389 (of 726) Pasifika adults were randomised to receive the mHealth intervention, while 405 (of 725) Pasifika adults were randomised to receive a control version of the intervention. Culturally relevant data was collected to examine holistic health and wellbeing status, at baseline, and at 12 weeks (end of the trial). The intervention effects and the association of demographic and behavioural relationships with wellbeing, was examined using logistic regression analyses.

**RESULTS:** Relative to baseline, there were significant differences between the intervention and control groups for the 'family/community' wellbeing, at the end of the 12-week trial. There were no significant differences observed for all other wellbeing domains for both groups. Based on our multivariate regression analyses, education and acculturation (assimilation and marginalisation) were identified as positively strong factors associated to Pasifika 'family and community' wellbeing.

**CONCLUSION:** Our study provides new insights on how Pasifika peoples' characteristics and behaviours align to wellbeing. Our findings point to 'family and community' as being the most important wellbeing factor for Pasifika peoples.

In New Zealand, obesity, prediabetes and T2DM are serious non-communicable (NCD) diseases that have an impact on overall health and wellbeing.[1] New Zealand has the third highest obesity (ie, BMI >30kg/m$^2$) rates (31%) (following Mexico and the US).[2] These diseases pose a major challenge for healthcare in New Zealand, place a substantial social-economic burden on the health system,[3–6] and are the leading drivers for health inequalities, particularly among New Zealand Pacific peoples.[1] Pacific peoples in New Zealand make up 7% of the total population,[7] and they have the highest rate (67%) of obesity, compared to Māori (indigenous people of New Zealand) (47%), and the non-Māori non-Pacific population (32%).[8] Little is known about how New Zealanders manage the challenges imposed by these conditions on wellbeing. Reducing the incidence and disease impact remains a key issue in disease prevention, and there is a major knowledge gap in how to tailor prevention programmes for sustainable healthier lifestyle change.[9]

With the scale of the rising NCD problem being more evident among Pacific peoples, recent work has highlighted that a focus on health and wellbeing required in-depth knowledge of: lifestyle factors (eg, poor diet); systemic issues (eg, lack of knowledge); and further understanding of the role of cultural and family responsibilities on Pacific people's overall health. Through better knowledge and understanding of these issues, effective prevention programmes that place health and well-being as a holistic focus[10] are considered to be better aligned with Pacific peoples' cultural and value systems. Researchers have also called for interventions to be ethnic-specific and culturally safe,[11] and for programmes that are inclusive of health and wellbeing from a Pacific viewpoint.[10] There have been many efforts to develop and implement culturally appropriate intervention programmes;[12,13] however, these programmes were not planned, developed, piloted or evaluated with the Pacific communities playing an equal partnership role at the helm of the project.

Mobile health (mHealth) programmes, that is, the use of mobile and wireless tools,[14] have been shown to aid the improvement in reducing NCD risk factors and develop healthy behavioural changes.[15,16] The OL@-OR@ project was a culturally tailored mHealth programme,[17] co-designed between New Zealand health researchers and Māori and Pasifika (defined as a collective group of people representing different Pacific Island Nations[18]) communities.[19] We will refer to Pacific peoples as Pasifika peoples from here onwards. The project employed co-design principles and methods to develop a pragmatic mHealth intervention tool with communities to support better health and wellbeing, through improved nutrition, healthy behaviours and to build better knowledge and awareness of community-level activities, resources and social cohesion. The co-design principles aligned well with indigenous health frameworks, and therefore it was considered to be a good fit, and likely to be well accepted,[9] by Pasifika communities.

This paper presents analyses of secondary outcomes of the cRCT and aims to determine the effects of the co-designed mHealth intervention on the wellbeing of Pasifika communities, and to identify the demographic and behavioural factors associated with enhanced wellbeing.

# Methods

The OL@-OR@ mHealth programme focused on managing or reducing the key risk factors for NCDs (eg, diet, physical activity, smoking, alcohol). The co-design approach enabled Pasifika communities to include a cultural measure of health that was holistic, Pasifika values-based, and included family and cultural identity as the foundation of health and wellbeing. The Pacific model of health (Fonofale)[20] includes four dimensions of health, namely: spiritual, physical, mental and other, and was used to inform the wellbeing measurements (Appendix 1) used in the OL@-OR@ mHealth programme.

The OL@-OR@ mHealth programme was implemented in a 12-week, community-based two-arm, cluster randomised control trial (cRCT) design, administered from between January–December 2018. Eligibility to participate in the trial included self-identification as being Māori or Pasifika, aged ≥18 years, regular mobile device access (eg, smartphone, laptop), regular internet access, and an email account. The main findings of the cRCT intervention have been published, and the trial protocol adheres to the SPIRIT guidelines, which has been published elsewhere and included as Appendix 1.[21] However, briefly, the participants were recruited predominantly via face-to-face from 64 community clusters (32 Māori, 32 Pasifika), and these were defined as a distinct New Zealand community context with an average of 20 participants per cluster. For Pasifika clusters, these included groups or communities (eg, churches, sports clubs), as identified by the Pasifika community coordinators (employed by the Pasifika community research partners). All clusters were randomly allocated (1:1 ratio) to either the intervention (mHealth tool) or the control (a control version of the mHealth tool that only selected collected data) group using a computer-generated randomisation list, and block randomisation was used to stratify Pasifika clusters by locality (Auckland/urban or Waikato/rural). The risk of contamination between cluster arms was minimised by

recruitment across large geographic areas and multiple diverse community.

Ethical approval for the trial was received from the Northern B Health and Disability Ethics Committee of New Zealand (OL@-OR@) in 2017. All clusters provided written informed consent, and individual participants provided informed consent via an online questionnaire completed at registration.

Pasifika participants in the initial phase of this study, provided an end-user perspective, contributing to the design of the intervention tool, design of outcome measures, analysis of qualitative data, and recruitment pathways for the cRCT. As a secondary outcome measure of the overall cRCT, we included the focus on holistic health and wellbeing status from a Pasifika perspective,[22] and this was compared between trial arms.

## Study outcomes and analyses

The original sample size calculation was based on the primary outcome for the overall cRCT; self-reported adherence to health-related behaviour guidelines,[17] and included complete data from 69 clusters (based on 80% power at a 5% level of significance (two-sided) to detect between group absolute difference of 15% in the primary outcome at 12 weeks post-randomisation). At baseline there were 69 clusters and 1,451 participants (657 Māori and 794 Pasifika), and 84% completed the 12-week follow-up questionnaire (n=1,224).

For the current paper, the Pasifika wellbeing data was extracted as a focus for this investigation, and therefore, all Pasifika participants were included in the analyses, irrespective of whether the participants in each cluster received or used the intervention. In addition, clusters that withdrew from the study or did not register any participants at baseline were excluded. Thus, the overall sample included in this paper was 794 Pasifika (controls n=405 and intervention group n=389). Continuous and categorical variables were presented as numbers observed, means and 95% confidence limits. Analyses were performed using SAS 9.4 (SAS Institute Inc., Cary NJ, US). All statistical tests of significance were based on paired t-tests, t-tests, using the conventional $p<0.05$.

## Defining wellbeing

We defined five areas of 'wellbeing' based on the individual variables that were aligned to the four pillars of the Fonofale model of health, and according to *a priori* knowledge and understanding of Pasifika health and wellbeing, as developed from our previous work.[10] This included; **spiritual wellbeing**: defined as, 'spiritual beliefs supporting health' measured on a 5-point Likert scale (*1=not very likely to 5=very likely*); **physical wellbeing** defined as, 'being physically ambulant (without pain)', all answers were measured on a 5-point Likert scale (*1=not very able to 5=very able*); **mental wellbeing** defined as 'how likely are setting family goals' and 'having a positive outlook about life in general'. Each question were measured on a 5-point Likert scale (*1=not very able/not very positive to 5=very able/very positive*); and '**family and community life'** was determined by 'how families rated their capacity to support healthier choices' and 'environments that support healthy choices'. All answers were measured on a 5-point Likert scale (1=*not very strong at all/not very well at all to 5=very strong/very well*). We also aggregated other variables that had indicated significance (data not shown in this paper), to formulate a single '**combined wellbeing'** variable. This included spiritual, physical and mental domains (including: spiritual beliefs, eating the right-sized portions at social events, mental goals and positive outlook on life). They were considered to be important aspects of wellbeing to our study participants, but not a sufficiently meaningful variable on its own, hence the aggregated approach. Each of these wellbeing variables were measured on a 5-point Likert scale (*1=not very able/not very confident at all/not very positive at all to 5=very able/very confident/very positiv*e). From here onwards, we will refer to these as the 'domains of wellbeing'.

Complementing the findings of the overall cRCT[21] this paper presents Pasifika data examining the relationship between the 'factors of wellbeing' (dependent variables) with demographics/behaviours (independent variables): **Socio-demographic data:** age, gender, ethnicity, highest education level; **Anthropometry:** self-reported weight (in kilograms) and height

(in centimetres); **Co-morbidities:** self-reported health condition(s) defined as being told by a doctor that they have high blood pressure, high cholesterol, diabetes and/or heart disease; and **Acculturation: Pasifika and Kiwi-New Zealand Heritage and Lifestyle:** Attitudes and beliefs about Pacific and Kiwi/New Zealand heritage and lifestyle measured using an eight-item cultural affiliation questionnaire.[23] The acculturation tool used in this study was developed by researchers of the Kohala Health Research Project,[24] and is a validated tool for adult Pasifika peoples examining similar health outcomes (metabolic health problems).[24] In accordance with the Kohala Health Research Project guidance, we analysed the responses by grouping the summed responses into the following categories: *integrated* (high affiliation with Pacific heritage and mainstream culture); *tradition* (high affiliation with Pacific heritage only); *assimilated* (high affiliation with mainstream culture only); and *marginalised* (low affiliation with both Pacific heritage and mainstream culture).

# Results

## Demographics

Table 1 shows the characteristics of all Pasifika study participants. The study communities were mostly located in urban centres (69.5%). The highest education qualifications obtained from the participants was at secondary school (45.0%) and tertiary (32.8%) levels, and the majority of participants were female (65.5%).

A wide range of Pacific Island nations were represented in the study, with the majority being Samoan (28.3%), Cook Island Māori (25.3%), and Tongan (19.7%). We grouped the remainder under 'Other Pacific Islands' because the numbers were too small to include independent island nations on their own.

Age was categorised into approximate quartiles: 18–24 (17.5%); 25–34 years (26.3%); 35–44 years (26.3%) and 45+ (29.9%).

A large proportion (67.6%) of the study participants assessed their acculturation mode as being '*marginalised*', indicating they had a low degree of affiliation with *both* their Pacific heritage and the mainstream culture.

Overwhelmingly, obesity BMI (30+) was highly prevalent among the entire Pasifika study sample (69.9%), and this is analogous for both the intervention (69.6%) and control (70.3%) groups. The participants presented with co-morbidities based on known diagnosis: high blood pressure being the most commonly reported. We also included a grouped variable ('any') to include all known morbidities. There were no significant differences indicated between the co-morbidity groups.

Table 2 examines the group means (standard deviations) for intervention and control participants at baseline and at 12 weeks. At baseline, there was no significant difference between these two groups. However, at 12 weeks, there was a significant difference between intervention and control groups, for the 'family and community' wellbeing (t-test p-value=0.007).

Relative to baseline, based on the mean differences (95%CI), both groups showed no change for 'spiritual', 'physical' and 'mental' and 'combined' factors of wellbeing. However, there was a significant difference between intervention and control groups for the 'family and community', at the end of the 12-week trial (t-test p-value=0.006).

Table 3 summarises the univariate analyses, examining the relationships between each 'factor of wellbeing' and the demographic and behavioural variables, at baseline.

For **spiritual wellbeing:** the strongest associations were age (oldest group) (p=0.0001); Other Ethnicity (p=0.0001); being *assimilated* (p=0.0001) and *marginalised* (p=0.0001).

As to the **physical wellbeing** factor, the strongest associations were: the older age groups (35–44 (p=0.0005); and 45 years (p=0.0008); those reporting extreme obesity (BMI 40+) (p=0.0001), and missing obesity data (p=0.015); and participants who identified as being *assimilated* (p=0.035); *traditional* (p=0.0005); and *marginalised* (p=0.0001), and having a co-morbidity (p=0.004).

**Table 1:** Distribution of Pasifika participant characteristics, at baseline.

| | All | | Intervention | | Control | |
|---|---|---|---|---|---|---|
| | 794 (n) | % | 389 (n) | % | 405 (n) | % |
| **Gender** | | | | | | |
| Male | 232 | 34.5 | 117 | 34.2 | 115 | 34.9 |
| Female | 440 | 65.5 | 225 | 65.8 | 215 | 65.2 |
| Missing | 1 | | | | | |
| **Ethnicity** | | | | | | |
| Tokelauan | 16 | 2.0 | 9 | 2.3 | 7 | 1.7 |
| Fijian | 7 | 0.9 | 4 | 1.0 | 3 | 0.7 |
| Niuean | 59 | 7.4 | 21 | 5.4 | 38 | 9.4 |
| Tongan | 156 | 19.7 | 114 | 29.3 | 42 | 10.4 |
| Cook Island Māori | 201 | 25.3 | 94 | 24.2 | 107 | 26.4 |
| Samoan | 225 | 28.3 | 95 | 24.4 | 130 | 32.1 |
| Other Pacific Island | 8 | 1.0 | 5 | 1.3 | 3 | 0.7 |
| Māori | 48 | 6.1 | 12 | 3.1 | 36 | 8.9 |
| NZ/Other European | 46 | 5.8 | 13 | 3.3 | 33 | 8.2 |
| Other | 28 | 3.5 | 22 | 5.7 | 6 | 1.5 |
| **Highest education** | | | | | | |
| Secondary school | 335 | 45.0 | 167 | 46.4 | 168 | 43.6 |
| Trade certificates | 52 | 7.0 | 27 | 7.5 | 25 | 6.5 |
| Tertiary (any level) | 244 | 32.8 | 103 | 28.6 | 141 | 36.6 |
| None | 114 | 15.3 | 63 | 17.5 | 51 | 13.3 |
| Missing | 49 | | | | | |
| **Age group (quartiles)** | | | | | | |
| 18–24 years | 139 | 17.5 | 67 | 17.2 | 72 | 17.8 |
| 25–34 years | 209 | 26.3 | 81 | 20.8 | 128 | 31.6 |
| 35–44 years | 209 | 26.3 | 104 | 26.7 | 105 | 25.9 |
| 45+ | 237 | 29.9 | 137 | 35.2 | 100 | 24.7 |
| **Region** | | | | | | |
| Urban | 552 | 69.5 | 279 | 71.7 | 273 | 67.4 |
| Rural | 242 | 30.5 | 110 | 28.3 | 132 | 32.6 |
| **BMI class** | | | | | | |
| Underweight (<18.50) | 2 | 0.3 | 1 | 0.3 | 1 | 0.3 |
| Healthy weight (18.50-24.99) | 73 | 11.3 | 41 | 12.7 | 32 | 9.8 |
| Overweight (25.00-29.99) | 120 | 18.5 | 56 | 17.4 | 64 | 19.6 |
| Obese (30+) | 453 | 69.9 | 224 | 69.6 | 229 | 70.3 |
| BMI missing | 146 | | | | | |

**Table 1:** Distribution of Pasifika participant characteristics, at baseline (continued).

| | | | | | | |
|---|---|---|---|---|---|---|
| **Co-morbidities** | | | | | | |
| High blood pressure | 108 | 13.6 | 57 | 14.7 | 51 | 12.6 |
| High cholesterol | 65 | 8.2 | 31 | 8.0 | 34 | 8.4 |
| Diabetes | 76 | 9.6 | 38 | 9.8 | 38 | 9.4 |
| Heart disease | 19 | 2.4 | 11 | 2.8 | 8 | 2.0 |
| **Acculturation** | | | | | | |
| Integrated | 118 | 14.9 | 49 | 12.6 | 69 | 17.1 |
| Traditional | 66 | 8.3 | 25 | 6.4 | 41 | 10.2 |
| Assimilated | 73 | 9.2 | 39 | 10.0 | 34 | 8.4 |
| Marginalised | 535 | 67.6 | 276 | 71.0 | 259 | 64.3 |
| Missing | 2 | | | | | |

For the **mental wellbeing** factor, the relationships were evident among those: in the oldest age group (45+years), p=0.011; participants who were from the Other Pacific Island nations (p=0.009) and Others (p=0.007); having only secondary school qualifications (p=0.010); and participants whose scores identified them as being *assimilated* (p=0.0001)*, traditional* (p=0.009) and *'marginalised'* (p=0.0001).

Under the **family/community** wellbeing factor, the following positive associations with demographic factors were highlighted: from those among the oldest age group (p=0.0001); being from 'Other Pacific Island' nations (p=0.002); participants with the lowest education qualifications: 'none' and 'secondary', p=0.021 and p=0.006, respectively; those who aligned with being *'assimilated'* (p=0.004); *'traditional'*

**Table 2:** Effect of wellbeing factors based on the mHealth programme, at 12 weeks from baseline.

| **Factors of wellbeing** | **Intervention baseline (n=389)** | | **Control baseline (n=405)** | | **Intervention 12 weeks (n=347)** | | **Control 12 weeks (n=369)** | | **Intervention vs control 12 weeks** | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **Mean** | **SD** | **Mean** | **SD** | **Mean** | **SD** | **Mean** | **SD** | **Intervention mean* (95%CI)** | **Control mean* (95%CI)** |
| Spiritual | 3.8 | 1.2 | 3.7 | 1.3 | 3.8 | 1.2 | 3.7 | 1.3 | 0.00 | 0.00 |
| Physical | 4.2 | 0.9 | 4.1 | 1.0 | 4.2 | 0.9 | 4.1 | 1.0 | 0.10 (-0.04–0.24) | -0.02 (-0.13–0.8) |
| Mental[a] | 7.9 | 1.7 | 7.8 | 1.7 | 8.1 | 1.6 | 7.9 | 1.5 | 0.22 (0.04–0.40) | 0.04 (-0.14–0.21) |
| Family/ community[a] | 7.1 | 1.8 | 7.1 | 1.8 | 7.6 | 1.6 | 7.3 | 1.6 | **0.54 (0.34–0.74)** | **0.17 (-0.03–0.36)** |
| Combined wellbeing[b] | 15.2 | 3.1 | 15.0 | 2.9 | 15.6 | 2.9 | 15.4 | 2.8 | 0.43 (0.11–0.75) | 0.38 (0.07–0.69) |

[a,b]=aggregate variables (see earlier for composition); SD=standard deviation; *=Difference between means, 95%CI= 95% confidence intervals.

**Table 3:** Wellbeing model: univariate analyses at baseline, by participant characteristics.

| | Factors of Pacific wellbeing | | | | | |
|---|---|---|---|---|---|---|
| | (n) | Spiritual wellbeing | Physical wellbeing | Mental wellbeing | [a]Family and community | [b]Combined wellbeing |
| **Characteristics** | | **mean (95CI)** | **mean (95CI)** | **mean (95CI)** | **mean (95CI)** | **mean (95CI)** |
| **Gender** | | | | | | |
| Male | 253 | 3.79 (3.63–3.94)[R] | 4.16 (4.04–4.28)[R] | 7.88 (7.67–8.09)[R] | 7.01 (6.79–7.23)[R] | 15.15 (14.78–15.52)[R] |
| Female | 540 | 3.77 (3.66–3.87) | 4.16 (4.08–4.24) | 7.88 (7.74–8.03) | 7.19 (7.04–7.34) | 15.13 (14.87–15.38) |
| Missing | 1 | | | | | |
| **Age group (quartiles)** | | | | | | |
| 18–24 years | 139 | 3.53 (3.32–3.73)[R] | 4.46 (4.30–4.62)[R] | 7.78 (7.50–8.06)[R] | 6.82 (6.53–7.11)[R] | 14.93 (14.45–15.42)[R] |
| 25–34 years | 209 | 3.61 (3.44–3.77) | 4.20 (4.07–4.33) | 7.68 (7.45–7.91) | 6.76 (6.52–6.99) | 14.47 (14.08–14.87) |
| 35–44 years | 209 | 3.71 (3.55–3.88) | **3.98 (3.85–4.11)**** | 7.76 (7.53–7.99) | 7.19 (6.95–7.43) | 14.99 (14.59–15.38) |
| 45+ years | 237 | **4.12 (3.96–4.27)**** | **4.11 (3.99–4.24)**** | **8.23 (8.02–8.45)*** | 7.60 (7.38–7.82)** | **15.96 (15.58–16.33)**** |
| **Ethnicity** | | | | | | |
| Samoan | 225 | 3.91 (3.75–4.07)[R] | 4.16 (4.04–4.29)[R] | 7.95 (7.73–8.17)[R] | 7.07 (6.84–7.30)[R] | 15.21 (14.83–15.60)[R] |
| Tokelauan | 16 | 3.81 (3.22–4.40) | 4.13 (3.65–4.60) | 7.75 (6.93–8.57) | 6.31 (5.45–7.18) | 15.44 (14.00–16.88) |
| Fijian | 7 | 4.00 (3.11–4.89) | 4.00 (3.28–4.72) | 7.57 (6.33–8.82) | 7.43 (6.12–8.74) | 15.71 (13.53–17.89) |
| Niuean | 59 | 3.71 (3.40–4.02) | 4.31 (4.06–4.55) | 7.75 (7.32–8.17) | 6.97 (6.52–7.42) | 14.59 (13.84–15.34) |
| Tongan | 156 | 4.15 (3.96–4.34) | 4.15 (3.99–4.30) | 8.08 (7.82–8.35) | 7.22 (6.94–7.50) | 15.76 (15.29–16.22) |
| Cook Island Māori | 201 | 3.70 (3.53–3.86) | 4.24 (4.10–4.37) | 8.04 (7.81–8.28) | 7.39 (7.14–7.63) | 15.32 (14.91–15.73) |
| Other Pacific Island | 8 | 3.25 (2.41–4.09) | 3.63 (2.95–4.30) | **6.38 (5.21–7.54)*** | **5.13 (3.90–6.35)*** | 13.00 (10.96–15.04)* |
| Other | 122 | **3.20 (2.99–3.42)**** | 4.03 (3.86–4.21) | **7.44 (7.14–7.74)*** | 7.02 (6.71–7.34) | 14.20 (13.67–14.72)* |
| **Highest education qualification** | | | | | | |
| Tertiary (any level) | 244 | 3.81 (3.66–3.97)[R] | 4.22 (4.10–4.34)[R] | 8.10 (7.89–8.32)[R] | 7.40 (7.18–7.63)[R] | 15.34 (14.96–15.71)[R] |
| None | 114 | 3.77 (3.54–4.00) | 4.16 (3.98–4.34) | 7.75 (7.44–8.06) | **6.94 (6.61–7.26)*** | 15.11 (14.57–15.66) |
| Secondary | 335 | 3.71 (3.58–3.84) | 4.16 (4.05–4.26) | **7.74 (7.56–7.92)*** | **6.99 (6.80–7.18)*** | 14.93 (14.61–15.25) |
| Trade | 52 | 3.83 (3.49–4.16) | 4.00 (3.74–4.26) | 7.92 (7.46–8.38) | 7.04 (6.56–7.52) | 15.21 (14.40–16.02) |
| Missing | 49 | 3.96 (3.61–4.31) | 4.12 (3.85–4.40) | 8.06 (7.59–8.53) | 7.33 (6.83–7.82) | 15.45 (14.61–16.28) |
| **Obese class** | | | | | | |
| Not obese | 195 | 3.64 (3.46–3.81)[R] | 4.34 (4.20–4.47)[R] | 7.78 (7.54–8.02)[R] | 7.21 (6.96–7.46)[R] | 15.20 (14.78–15.62)[R] |
| Obese class 1 (BMI 30-34.99) | 144 | 3.83 (3.62–4.03) | 4.28 (4.13–4.44) | 7.90 (7.62–8.17) | 7.06 (6.76–7.35) | 15.15 (14.66–15.63) |
| Obese class 2 (BMI 35-39.99) | 131 | 3.78 (3.57–3.99) | 4.24 (4.08–4.41) | 7.99 (7.70–8.28) | 6.87 (6.56–7.18) | 15.07 (14.56–15.58) |
| Obese class 3 (BMI 40+) | 178 | 3.80 (3.62–3.99) | **3.88 (3.74–4.02)**** | 7.97 (7.72–8.22) | 7.24 (6.98–7.50) | 14.97 (14.53–15.40) |
| Missing | 146 | 3.86 (3.66–4.06) | **4.08 (3.93–4.24)*** | 7.80 (7.53–8.08) | 7.21 (6.92–7.50) | 15.29 (14.81–15.78) |

**Table 3:** Wellbeing model: univariate analyses at baseline, by participant characteristics (continued).

| | | | | | | |
|---|---|---|---|---|---|---|
| **Acculturation** | | | | | | |
| Integrated | 118 | 3.12 (2.91–3.33)[R] | 3.75 (3.58–3.93)[R] | 6.60 (6.32–6.89)[R] | 5.95 (5.64–6.25)[R] | 12.77 (12.27–13.27)[R] |
| Assimilated | 73 | **3.88 (3.61–4.15) **** | **4.05 (3.83–4.27)*** | **7.85 (7.49–8.21)**** | **6.67 (6.28–7.06)*** | **15.11 (14.48–15.74)**** |
| Traditional | 66 | 3.09 (2.81–3.38) | **4.27 (4.04–4.50)**** | **7.24 (6.86–7.62)*** | **6.83 (6.43–7.24)**** | **13.92 (13.26–14.59)*** |
| Marginalised | 535 | **3.98 (3.88–4.08) **** | **4.25 (4.17–4.33)**** | **8.25 (8.11–8.38)**** | **5.95 (5.64–6.25)**** | **15.81 (15.57–16.04)**** |
| Missing | 2 | | | | | |
| **Region** | | | | | | |
| Urban | 552 | 3.83 (3.72–3.93)[R] | 4.14 (4.06–4.22)[R] | 7.86 (7.72–8.01)[R] | 7.04 (6.89–7.18)[R] | 15.07 (14.82–15.32)[R] |
| Rural | 242 | 3.65 (3.50–3.81) | 4.21 (4.08–4.33) | 7.93 (7.71–8.14) | **7.35 (7.13–7.58)*** | 15.28 (14.91–15.66) |
| **Comorbidities (Any)** | | | | | | |
| No | 608 | 3.79 (3.69–3.89)[R] | 4.22 (4.14–4.29)[R] | 7.92 (7.79–8.06)[R] | 7.12 (6.98–7.26)[R] | 15.21 (14.97–15.45)[R] |
| Yes | 186 | 3.72 (3.54–3.90) | **3.98 (3.84–4.12)*** | 7.76 (7.51–8.00) | 7.17 (6.92–7.43) | 14.88 (14.45–15.31) |

[a]=Aggregate of family and community goals, active participation in community life, and rating of family's ability to make healthy choices; [b]=Aggregate of spiritual, dietary portions, mental wellbeing goals for family and positive view on life; R=referent group; *=p<0.05; **=p<0.001.

**Table 4:** Wellbeing model: multivariate regression (mean differences), from 12 weeks to baseline.

| **Characteristics** | **(n)** | **Spiritual wellbeing** | **Physical wellbeing** | **Mental wellbeing** | **[a]Family and community** | **[b]Combined wellbeing score** |
|---|---|---|---|---|---|---|
| **Gender** | | | | | | |
| Male | 226 | 0.19 (-0.09–0.46)[R] | 0.07 (-0.17–0.30)[R] | 0.32 (-0.06–0.70)[R] | 0.72 (0.30–1.14)[R] | 0.56 (-0.11–1.24)[R] |
| Female | 489 | 0.22 (-0.05–0.49) | 0.07 (-0.16–0.29) | 0.43 (0.05–0.80) | 0.81 (0.40–1.22) | 0.83 (0.17–1.49) |
| Missing | 1 | | | | | |
| **Age group (quartiles)** | | | | | | |
| 18–24 years | 118 | 0.39 (0.05–0.73)[R] | -0.08 (-0.36–0.21)[R] | 0.34 (-0.13–0.80)[R] | 0.76 (0.25–1.28)[R] | 0.90 (0.07–1.72)[R] |
| 25–34 years | 190 | **0.08 (-0.20–0.36)*** | 0.16 (-0.08–0.40) | 0.29 (-0.10–0.69) | 0.85 (0.42–1.28) | 0.58 (-0.11–1.27) |
| 35–44 years | 190 | 0.23 (-0.07–0.53) | **0.19 (-0.07–0.44)*** | 0.57 (0.15–0.98) | 0.83 (0.37–1.28) | 0.77 (0.04–1.50) |
| 45+ years | 218 | 0.11 (-0.18–0.39) | 0.00 (-0.24–0.24) | 0.30 (-0.09–0.69) | 0.62 (0.19–1.05) | 0.54 (-0.16–1.23) |
| **Ethnicity** | | | | | | |
| Samoan | 203 | 0.24 (-0.04–0.51)[R] | -0.08 (-0.36–0.21)[R] | 0.16 (-0.21–0.54)[R] | 0.65 (0.24–1.06)[R] | 0.84 (0.18–1.50)[R] |
| Tokelauan | 14 | 0.77 (0.11–1.42) | 0.16 (-0.08–0.40) | 0.37 (-0.53–1.28) | 0.89 (-0.11–1.89) | 1.07 (-0.53–2.68) |
| Fijian | 7 | 0.08 (-0.82–0.97) | 0.19 (-0.07–0.44) | 0.80 (-0.43–2.03) | 1.04 (-0.32–2.40) | 1.11 (-1.07–3.29) |
| Niuean | 54 | 0.11 (-0.27–0.49) | 0.00 (-0.24–0.24) | 0.40 (-0.13–0.92) | 0.62 (0.04–1.20) | 0.94 (0.01–1.87) |
| Tongan | 141 | 0.20 (-0.10–0.50) | -0.08 (-0.36–0.21) | 0.43 (0.02–0.84) | 0.84 (0.39–1.30) | 0.49 (-0.24–1.22) |
| Cook Island Māori | 185 | 0.20 (-0.07–0.47) | 0.16 (-0.08–0.40) | 0.07 (-0.31–0.44) | 0.40 (-0.01–0.81) | 0.68 (0.02–1.34) |
| Other Pacific Islands | 6 | 0.04 (-0.95–1.02) | 0.19 (-0.07–0.44) | 0.38 (-0.97–1.74) | 1.27 (-0.22–2.76) | -0.09 (-2.48–2.31) |
| Other | 106 | -0.01 (-0.31–0.28) | 0.00 (-0.24–0.24) | 0.38 (-0.02–0.79) | 0.40 (-0.05–0.85) | 0.52 (-0.21–1.24) |

**Table 4:** Wellbeing model: multivariate regression (mean differences), from 12 weeks to baseline (continued).

| | | | | | | |
|---|---|---|---|---|---|---|
| **Highest education qualification** | | | | | | |
| Tertiary (any level) | 223 | 0.16 (-0.11–0.44)[R] | 0.13 (-0.10–0.37)[R] | 0.22 (-0.16–0.61)[R] | 0.53 (0.11–0.95)[R] | 0.48 (-0.19–1.16)[R] |
| None | 107 | 0.18 (-0.14–0.50) | 0.12 (-0.15–0.39) | 0.58 (0.13–1.02) | **1.06 (0.57–1.55)*** | 1.05 (0.26–1.83) |
| Secondary | 293 | 0.11 (-0.15–0.38) | 0.08 (-0.15–0.30) | 0.39 (0.02–0.76) | 0.75 (0.34–1.15) | 0.71 (0.07–1.36) |
| Trade | 46 | 0.24 (-0.18–0.65) | 0.03 (-0.32–0.38) | 0.37 (-0.20–0.94) | 1.01 (0.38–1.64) | 0.79 (-0.22–1.80) |
| Missing | 47 | 0.31 (-0.11–0.74) | -0.02 (-0.38–0.33) | 0.31 (-0.27–0.90) | 0.47 (-0.17–1.11) | 0.45 (-0.59–1.48) |
| **Acculturation** | | | | | | |
| Integrated | 104 | 0.52 (0.20–0.83)[R] | 0.28 (0.01–0.55)[R] | 0.81 (0.37–1.25)[R] | 1.24 (0.76–1.72)[R] | 1.80 (1.03–2.58)[R] |
| Assimilated | 70 | **0.01 (-0.36–0.37)*** | 0.01 (-0.29–0.32) | **-0.01 (-0.51–0.49)*** | **0.47 (-0.08–1.02)*** | **-0.10 (-0.99–0.79)**** |
| Traditional | 59 | 0.17 (-0.24–0.57) | 0.06 (-0.28–0.40) | 0.43 (-0.13–0.98) | 0.83 (0.22–1.45) | 0.88 (-0.11–1.86) |
| Marginalised | 481 | **0.12 (-0.13–0.37)*** | **-0.09 (-0.29–0.12)*** | **0.27 (-0.07–0.61)*** | **0.51 (0.14–0.89)**** | **0.20 (-0.40–0.81)**** |
| Missing | 2 | | | | | |
| **Region** | | | | | | |
| Urban | 503 | 0.16 (-0.10–0.41)[R] | 0.01 (-0.20–0.22)[R] | 0.29 (-0.05–0.63)[R] | 0.66 (0.29–1.04)[R] | 0.44 (-0.64–1.51)[R] |
| Rural | 213 | 0.25 (-0.11–0.60) | 0.13 (-0.13–0.38) | 0.46 (0.04–0.88) | 0.86 (0.40–1.33) | 0.51 (-0.63–1.65) |
| **Comorbidities (any)** | | | | | | |
| No | 553 | 0.19 (-0.06–0.44)[R] | 0.01 (-0.20–0.22)[R] | 0.29 (-0.05–0.63)[R] | 0.66 (0.29–1.04)[R] | 0.44 (-0.64–1.51)[R] |
| Yes | 163 | 0.21 (-0.09–0.52) | 0.13 (-0.13–0.38) | 0.46 (0.04–0.88) | 0.86 (0.40–1.33) | 0.51 (-0.63–1.65) |

[R]=Referent group; [a]=Aggregate of family and community goals, active participation in community life, and rating of family's ability to make healthy choices; [b]=Aggregate of spiritual, diet, mental wellbeing goals for family and positive view on life; *=p<0.05; **=p<0.001.

(p=0.0007); and *'marginalised'* (p=0.0001), and participants from the 'rural' cluster localities (p=0.021).

The **combined wellbeing** factor showed significant positive relationships with participants: in the oldest age group (45+yrs) (p=0.0011); being from Other Pacific Island' nations (p=0.037), and 'Other' (p=0.002) ethnic groups; and those who rated their acculturation status as being *assimilated* (p=0.0001); *traditional* (p=0.007), and *marginalised* (p=0.0001), all significantly reported alignment with this wellbeing factor.

Informed by our univariate analyses (Table 3), Table 4 includes the *potential* independent variables in our multivariate analyses of all participants that provided data at both baseline and at 12 weeks. We excluded BMI and obesity class variables from this analyses as (from earlier models) their significant levels consistently diminished and it was no longer meaningful to retain them in the model. The independent variables were examined by way of mean differences (95CI) from 12 weeks to baseline, for each factor of wellbeing. Notably, only the significant relationships are highlighted in the table.

For the **spiritual wellbeing factor**, after adjusting for all co-variates: being of young age (25–34 years) p=0.031; and acculturation (*assimilation and marginalised)* p=0.008 and 0.003, respectively, sustained significant improved relationships with this wellbeing factor.

Under the **physical wellbeing factor**, after adjusting for sex, age, ethnicity, education, cluster region and having any comorbidity, only the participants who were aged 35–44 years (p=0.030) retained a positive association with physical wellbeing. Conversely, those who rated as being *'marginalised'* (p=0.001) had a very small negative mean difference that was significant, albeit indicating no improvement (-0.09) compared to the *'integrated'* group, by the end of the trial.

As for the **mental wellbeing**, after adjusting for all variables, only acculturation sustained a significant relationship with this wellbeing factor. Participants that aligned with being *'assimilated'* had shown a very small negative association, indicating no improvement (-0.01, 95CI: -0.51–0.49, p=0.002) at the end of the trial. Those participants that affiliated with being *'marginalised'* had sustained a positive significant relationship and they reported a mild improvement with mental wellbeing (0.27, 95CI: -0.07–0.61, p=0.004), compared to the *'integrated'* group.

For the **family/community** wellbeing, after controlling for all co-variates, the participants with 'no education' qualifications (1.06, 95CI: 0.57–1.55, p=0.019) showed a large significant (positive) improvement, compared to those participants with any 'tertiary level' qualifications (0.53, 95CI: 0.11–0.95). Regarding all acculturation modes, there were significant positive improvements for the *'marginalised'* group (p=0.0004), followed by the *'assimilated'* group (p=0.008), compared to the *'integrated'* group.

Finally, the **combined wellbeing** factor, after adjusting for all variables, the significant relationships were evident among those participants that corresponded to being *'assimilated'* (-0.10, 95CI: -0.99–0.79, p=0.0001) – showing no improvement for this wellbeing; and being *'marginalised'* (0.20, 95CI: -0.40–0.81, p=0.0001), when compared to the *'integrated'* group.

# Discussion

In our large mHealth cRCT programme, we defined the 'domains of wellbeing' as being: spiritual, physical, mental, family/community and a combined wellbeing domain, which was an aggregate of various wellbeing measurement scores (Appendix 2). These wellbeing factors were arbitrarily defined by how well the Pasifika participants rated their wellbeing status according to a range of individual characteristics (Table 1).

## Principal findings

There are three major findings from our analyses. Firstly, Table 2 showed significant differences between the intervention and control groups for 'family/community' wellbeing factor, by the end of the 12-week trial. This is not surprising, given that Pasifika peoples traditionally and have continue to live and participate in social cohesion. There were no differences between intervention and control groups for the remaining wellbeing factors, and this was analogous with the findings from the overall study,[21] that also demonstrated that the mHealth programme did not significantly improve adherence to health-related behaviours for all participants. This finding may be explained by the short duration of the trial (12 weeks), and it is possible that a longer duration may have provided more meaningful information.[21]

The remaining major findings were based on our multivariate analyses (Table 4). The second major finding was 'acculturation' as being a major determinant of wellbeing for our Pasifika participants. In particular, the acculturated modes, of being *'assimilated'* (*high affiliation with mainstream culture only*) and *'marginalised'* (*low affiliation with both Pacific heritage and mainstream culture*) were independently negatively associated with all wellbeing factors. Specifically, those participants who classified themselves as being *'assimilated'* showed either little or no association with 'spiritual', 'physical', 'mental' and 'combined' wellbeing factors. A possible explanation could relate to issues of adapting to the changing dynamics of traditional and cultural practices and values. On the other hand, significant positive associations were evident for those who classified themselves as being *'marginalised'* for all wellbeing factors (but not physical—very small negative association), and this could be an indicator of cultural resilience. Previous research has shown that some groups facing chronic stresses created by poverty, racism and discrimination due to a lack of security in identity and traditional values,[25] and therefore the scores in our study may reflect a lack of bicultural and societal identity.

Of note, the young and working age participants (25–34 years and 35–44 years) showed significant associations with the 'spiritual' and 'physical' wellbeing factors, which characterises their level of participation in community and church activities.

The third major finding of our study showed clear positive relationships between: 'no education', and acculturation modes: 'assimilation', and being

'marginalised', with the 'family/community' wellbeing factor. The high scores highlighted significant positive improvements by the end of the 12-week trial. A possible explanation for having a strong and diverse relationship of acculturation to this wellbeing factor could be related to how Pasifika peoples in our study connect to the Pasifika way of life (ie, cultural values and protocol). This may indicate the growing disconnect between and within Pasifika communities.[26] For example, symptoms of living in diasporic communities may be manifested in the way Pasifika peoples view and define their cultural identity as being 'born' or 'raised',[27] and the degree of 'how well' they affiliate with the mainstream and, or their Pasifika heritage.[22] In relation to education, participants with 'no education' had improved because of the programme, and this was evident in our qualitative data (not published), where participants reportedly learnt a lot about healthy lifestyles, because the mHealth tool was relevant to Pasifika culture and values.

## Implications of study

Acculturation has recently been redefined from a linear process in which one ethnic/cultural group adopt the beliefs and behaviours of another group,[28] to a multi-dimensional process where people engage in different ways.[29,30] The finding of associations among *'marginalised'* participants and 'family/community' wellbeing may be indicative of other complex psychosocial factors, such as attitudes, beliefs, emotions and learned behaviours, that have not been catered for in the current study.

Additionally, as the family/community context is a primary environment in which its members grow up and develop their identity, it is possible that the participants in this study experienced different distress and intra-familial stressors as a result of acculturation.[25] Therefore, acculturation responses are likely to be different, or conflicting based on personal experiences of acculturation and family/community cohesion.[31–33] Thus, the acculturation modes used in this study may only be representative of the participants' perspectives in relation to how we have defined 'family/community' wellbeing. Alternatively, the acculturation tool may not be adequately sufficient to measure the degree and variation of cultural heritage and affiliation. Observing how family and community members function as a nucleus or an extended network system of shared interests, values and experiences maybe a better alternative to understand wellbeing. Unfortunately, our study was not able to gauge participants' in-depth understanding of acculturation and family/community cohesion.

## Study limitations and future work

A major limitation is the potential for selection bias of study participants that may have led to the high proportion of participants indicating their acculturation status as being predominantly 'marginalised', and lower education background. Also, there is the potential for participation bias based on the limited use of the mobile/electronic platform of the intervention tool and due to the duration of the mHealth trial (12 weeks), that may have been too short to be able to measure the wellbeing factors at a comprehensive level. Finally, to better understand wellbeing from a Pasifika perspective, further research will be needed to include other domains outside of established health models, including the role of family and community.

# Conclusion

Our study utilised Pasifika-only participant data from a large cRCT[21] study, to examine the relationship between demographic and behavioural factors and Pasifika wellbeing. From the cRCT findings (Table 2), the programme appears to have supported positive changes, particularly for the intervention participants in 'family and community' wellbeing, compared with the controls. Additionally, it was clear from our multivariate analyses that at an individual level, the study participants who identified as being 'marginalised' had significantly positive associations with family/community wellbeing. Although the study findings do not fully explain the reasons behind the acculturation, education and age characteristics associations, it does point to the importance of 'family/community' as being the most important wellbeing factor for Pasifika peoples. Future work could focus on more in-depth understanding of the psychosocial factors and an up-to-date knowledge of intra-familial and inter-generational perception of acculturation, and its effect on overall wellbeing.

# Appendix

**Appendix Table 1:** Wellbeing questions: Pasifika version.

| | |
|---|---|
| **Spiritual** | 1. How do your spiritual beliefs support you to have a healthy life?<br>Likert scale not very well at all—> very well<br>Comment: *Free text* |
| **Physical (also covered with primary outcomes)** | 2. How able are you to move about without pain or discomfort?<br>Likert scale not very able at all—> very able<br>Comment: *Free text* |
| | 3. How confident are you in eating the right-sized portions at community events?<br>Likert scale not very confident at all—> very confident<br>Comment: *Free text* |
| **Mental** | 4. How able do you feel to set goals for yourself?<br>Likert scale not very able at all—> very able<br>Comment: *Free text* |
| | 5. How likely are you to set goals for yourself or your family?<br>Likert scale not very likely at all—> very likely<br>Comment: *Free text* |
| | 6. How positive are you about life in general?<br>Likert scale not very positive at all—> very positive<br>Comment: *Free text* |
| | 7. How much do you like participating in community activities?<br>Likert scale not very much at all—>very much<br>Comment: *Free text* |
| **Family** | 8. How strong would you rate your family's ability to make healthy choices?<br>Likert scale not very strong at all—> very strong<br>Comment: *Free text* |
| **Other** | 9. How well does the environment support you to make healthy choices? (environment includes physical, social, economic and political environment(s) and a range of settings such as schools, churches, food stores, sports clubs, etc)<br>Likert scale not very well at all—> very well<br>Comment: *Free text* |
| | 10. How well do you know how to access healthy services in your local community, eg, local markets, low-cost exercise classes, etc?<br>Likert scale not very well at all—> very well<br>Comment: *Free text* |

## Pacific and Kiwi/New Zealand heritage and lifestyle

| | | | | | |
|---|---|---|---|---|---|
| Next are questions about your attitude and beliefs about Pacific and Kiwi/New Zealand heritage and lifestyle. Please provide the answer that best describes you after each question | | | | | |
| **Pacific/Kiwi-New Zealand Heritage and Lifestyle** | | | | | |
| 1 = Very Knowledgeable, 2 = Somewhat Knowledgeable, 3 = Neutral or No response, 4 = Somewhat not knowledgeable, 5 = Not at all Knowledgeable | | | | | |
| **Questions** | 1 | 2 | 3 | 4 | 5 |
| 1. How knowledgeable are you of traditional **Pacific** culture and lifestyle? | | | | | |
| 2. How knowledgeable are you of traditional **Kiwi/ New Zealand** culture and lifestyle? | | | | | |
| 1 = Very involved, 2 = Somewhat involved, 3 = Neutral or No response, 4 = Somewhat not knowledgeable, 5 = Not at all involved | | | | | |
| **Questions** | 1 | 2 | 3 | 4 | 5 |
| 3. How involved are you in **Pacific** culture and lifestyle? | | | | | |
| 4. How involved are you in **Kiwi/New Zealand** culture and lifestyle? | | | | | |
| 1 = Very Positive, 2 = Somewhat Positive, 3 = Neutral or No response, 4 = Somewhat negative, 5 = Very Negative | | | | | |
| **Questions** | 1 | 2 | 3 | 4 | 5 |
| 5. How do you feel towards the **Pacific** culture and lifestyle? | | | | | |
| 6. How do you feel towards the **Kiwi/New Zealand** culture and lifestyle? | | | | | |
| 1 = Very Important 2 = Somewhat Important, 3 = Neutral or No response, 4 = Very little importance, 5 = Not important at all | | | | | |
| **Questions** | 1 | 2 | 3 | 4 | 5 |
| 7. How important is it for you to maintain a **Pacific** lifestyle and identity? | | | | | |
| 8. How important is it for you to maintain a **Kiwi/New Zealand** lifestyle and identity? | | | | | |

**Appendix Table 2:**

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 2 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | |
| Protocol version | 3 | Date and version identifier | 14 |
| Funding | 4 | Sources and types of financial, material, and other support | 15 |
| Roles and responsibilities | 5a | Names, affiliations and roles of protocol contributors | 1 |
| | 5b | Name and contact information for the trial sponsor | 1 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 15 |
| | 5d | Composition, roles and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | 15 |
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 3–4 |
| | 6b | Explanation for choice of comparators | 7 |
| Objectives | 7 | Specific objectives or hypotheses | 3–4 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory) | 4 |

| Methods: participants, interventions, and outcomes | | | |
|---|---|---|---|
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 4–5 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 4–5 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 6–7 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | N/A |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 7 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | N/A |
| Outcomes | 12 | Primary, secondary and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 7–10 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 11 |
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 10 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 5 |

| | | | |
|---|---|---|---|
| **Methods: assignment of interventions (for controlled trials)** | | | |
| **Allocation:** | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 6 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 6 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 6 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 6 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | N/A |
| **Methods: Data collection, management and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 7–10 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 7–10 |
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 12 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 11–12 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 11–12 |

| | | | |
|---|---|---|---|
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 13 |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | N/A |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | N/A |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 13 |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/ institutional review board (REC/IRB) approval | 13 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 13 |
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 13 |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | 14–15 |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during and after the trial | 12 |

| | | | |
|---|---|---|---|
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 15 |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 13 |
| Ancillary and post- trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | 13 |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 13–14 |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | 14 |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | N/A |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | Appendix 2 |
| Biological specimens | 33 | Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | N/A |

**Competing interests:**
Nil.

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