

The LvL UP Trial: Protocol for a Sequential, Multiple Assignment, Randomized Controlled Trial to Assess the Effectiveness of a Blended Mobile Lifestyle Intervention

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Introduction

Blended mobile health (mHealth) interventions – combining self-guided and human support components – could play a major role in preventing non-communicable diseases (NCDs) and common mental disorders (CMDs). This poster describes a sequential, multiple assignment, randomised trial (SMART) protocol aimed at:

- evaluating the effectiveness and cost-effectiveness of LvL UP, an mHealth intervention for the prevention of NCDs and CMDs, and
- establishing the optimal blended approach in LvL UP that balances effective personalised lifestyle support with scalability.

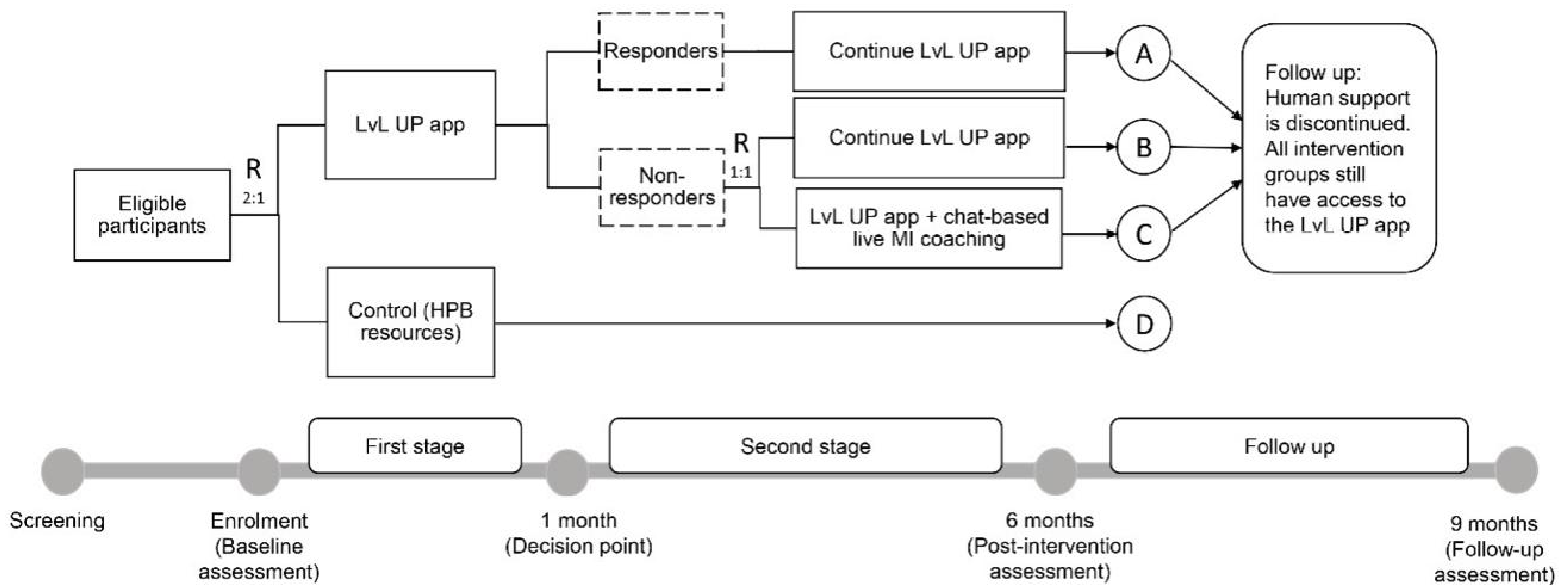


Figure 1. Sequential Multiple Assignment Randomization Trial (SMART) design for LvL UP. Note: letters A-D represent four subgroups in three different trial conditions, R = Randomisation ratio; MI = Motivational Interviewing; HPB = Health Promotion Board.

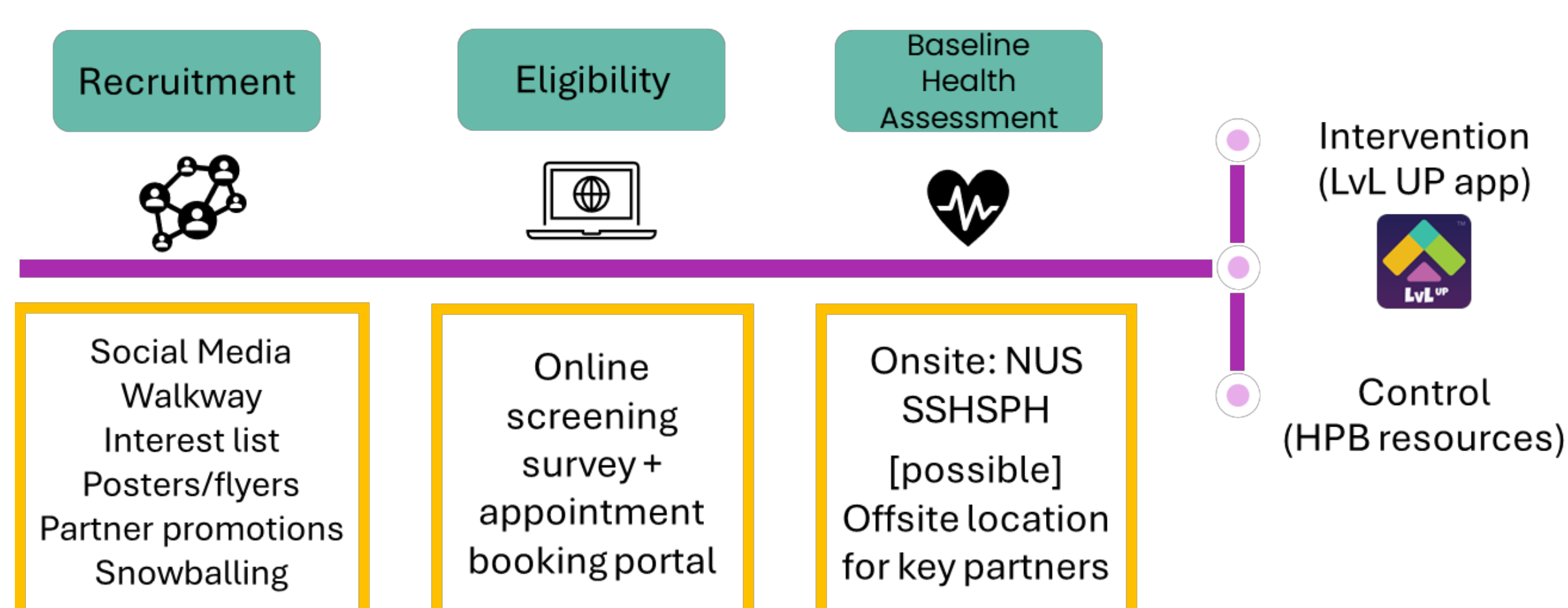
Methods: Intervention components & study design

- LvL UP is a 6-month mHealth holistic intervention targeting physical activity, diet, and emotional regulation. The intervention has been developed to facilitate the inclusion of an adaptive blended component for 'non-responders'.
- In the LvL UP trial, 650 participants will be randomly allocated to one of two initial conditions (LvL UP or 'comparison').
- After 1 month, participants from the LvL UP group categorised as non-responders (based on lack of engagement and/or preliminary intervention success) will be re-randomised into second-stage conditions (see Figure 1).



Methods: Outcomes & participant flow

- The primary outcome is mental well-being (via the Warwick-Edinburgh Mental Wellbeing Scale).
 - Secondary outcomes include anthropometrics, resting blood pressure, blood metabolic profile, health status, and health behaviours (physical activity, diet).
- Participant flow:



Methods: Eligibility criteria

Inclusion Criteria	Exclusion Criteria
- Aged 21 to 59 years	- Participants with a pre-existing NCD or CMD
- Singapore citizen or PR residing in Singapore for the duration of the study	- Currently taking medications known to influence blood pressure or glucose metabolism
- Able to speak/read English	- Pregnant
- Owners of a smartphone	- Currently enrolled in a lifestyle intervention study
- Identified as developing NCDs and/or CMDs based on a lifestyle composite score: including physical activity, diet, mental wellbeing, family history of health conditions and BMI	

Conclusions

- In addition to evaluating the effectiveness of LvL UP, the proposed study design will contribute to increasing evidence on how to introduce human support in mHealth interventions to maximise their effectiveness while remaining scalable.

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