Exploring Meaningful Change in Digital Health Technologies via Qualitative Interviews

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INTRODUCTION

Digital health technologies (DHTs), such as wearable devices or sensors, can be utilized to evaluate patient experiences in real world settings, often to complement self-reported data. As DHTs become accepted as primary or secondary endpoints in clinical trials, it is important to understand whether parameters assessed via DHTs reflect meaningful changes to patients. As part of a larger study, the authors piloted a vignette-based interview method to explore meaningful change in measurements of functional mobility (FM) that can be obtained via DHTs.

METHOD

Twenty-four adults living with obesity or overweight participated in individual 60-minute interviews, where a series of novel vignettes were debriefed. Vignettes focussed on four FM concepts, which participants in a previous interview study had identified as the most bothersome weight-related impacts: walking on a flat surface or uphill, moderate-to-vigorous physical activity (MVPA), climbing stairs, and standing. Each FM concept included a set of between four and six vignettes (e.g., Figure 1), and at the end of each set of vignettes, participants were asked to indicate which of the measurement options would be the most important to see an improvement in.

Each vignette depicted a **method of measuring the FM concept**, which was typically an improvement in either time (e.g., longest walk without a break), speed (e.g., average walking speed), distance (e.g., daily step count), or number of bouts (e.g., number of walks per day). Vignette concepts were chosen to align with measurements that can already be captured with existing DHTs.

Along with the specific measurement to be improved, each vignette included a **baseline ability level**, to guide the discussion and provide a starting point for each participant to consider what change would be meaningful to them. If the baseline ability level was not appropriate to the participant (i.e., it was significantly higher or lower than their current ability), the vignettes were programmed to allow the interviewer to select an alternative, custom baseline.

Three **thresholds for meaningful improvements** were provided for each vignette, calculated based on the baseline ability selected. Change in ability was expressed as a percentage (e.g., 25%/50%/100% improvement; Figure 2 and Figure 3) with equivalent units provided to help contextualize the improvements described (e.g., 2500/3000/4000 steps). The equivalent units were amended for any custom baselines chosen by participants, live during the interview. Participants were asked to select the smallest change that would be meaningful to them in each scenario. Open-ended interview questions were utilized to encourage the participants to explain why that change would be meaningful and how an improvement of that magnitude would impact their daily life and functioning.

Figure 2: A vignette slide presented to participants on the number of steps taken per day

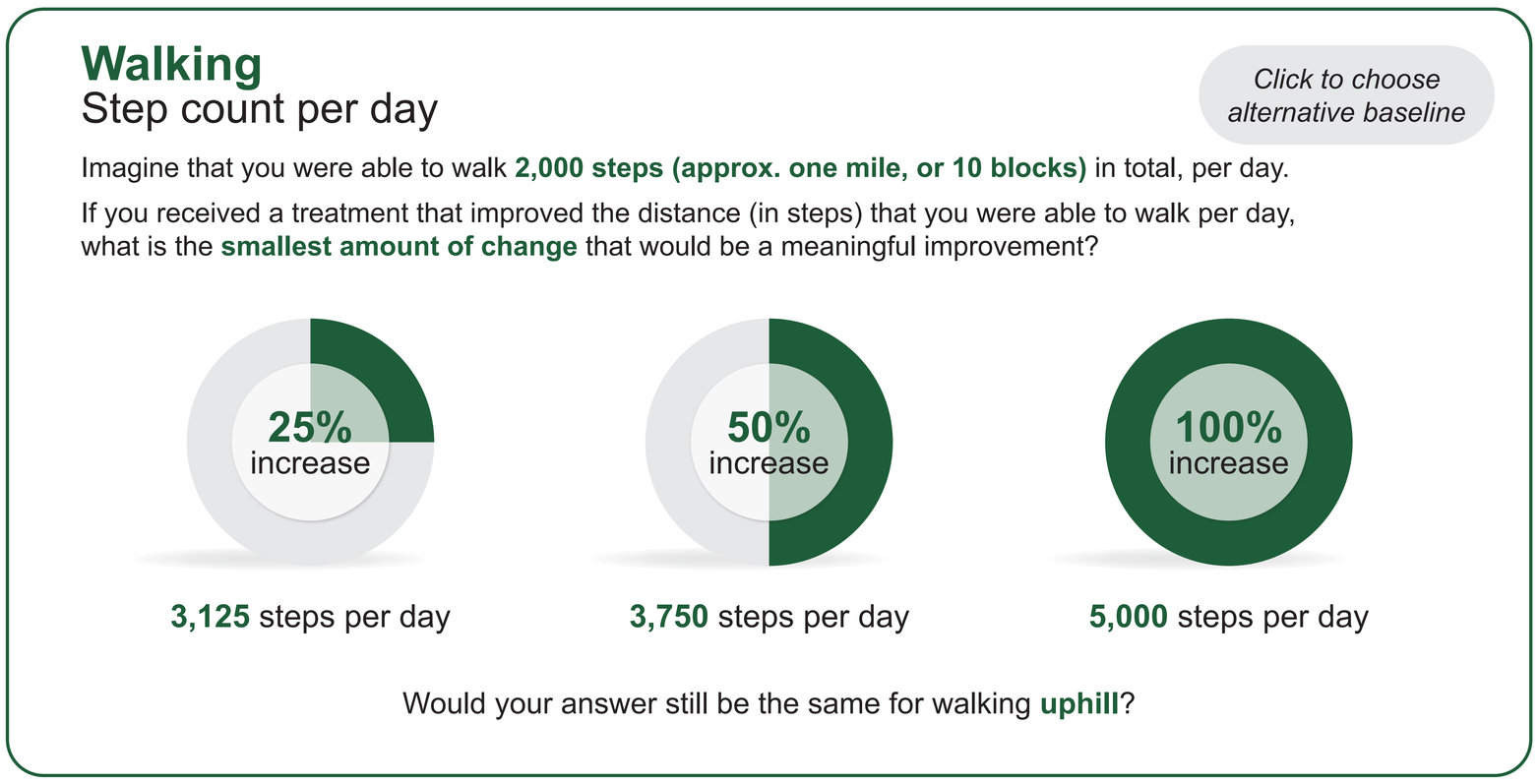


Figure 3: A vignette slide presented to participants on the longest time being physically active without a break

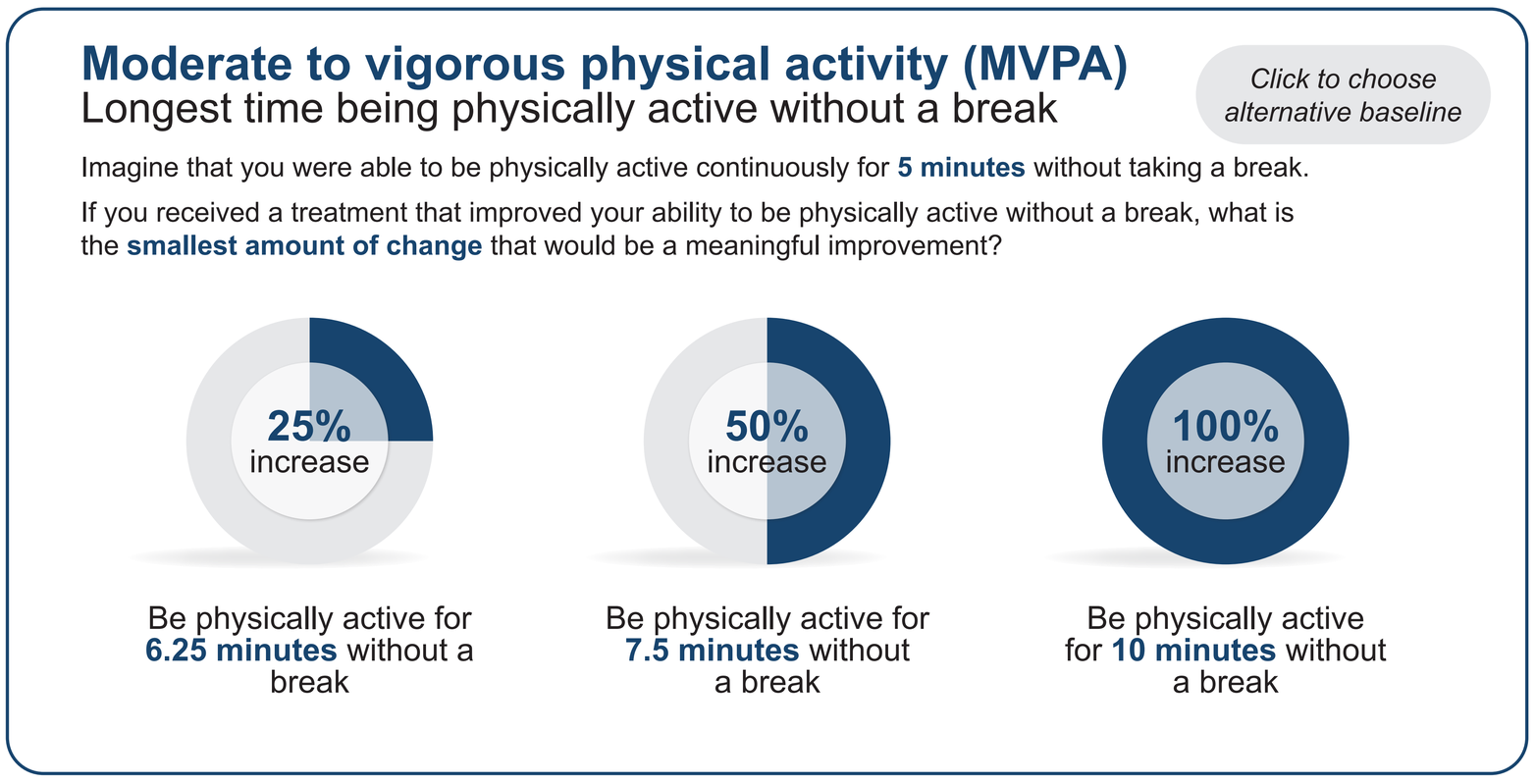
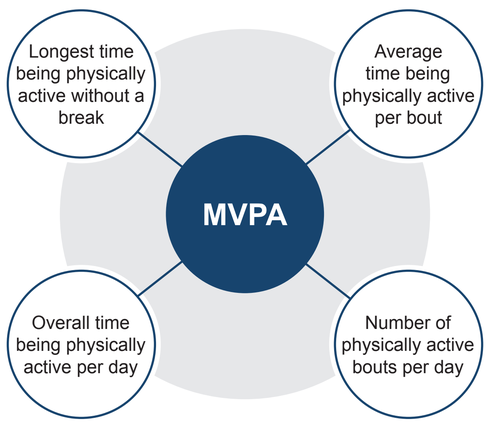


Figure 1: Example of the walking and MVPA concepts used in the vignettes

Walking:

Moderate to vigorous physical activity (MVPA):



RESULTS

Participant ages ranged from 20-82 years old, and 42% of the sample only held a high school diploma or had a lower education level. Participants did not express any difficulties understanding or completing the vignette exercise, although the pre-selected 'baseline' value was sometimes considered too low or too high to relate to. In these cases, participants provided their own baseline based on personal experience and the interviewer was then able to convert the unit-based response options to match the participant's personalised baseline.

Most participants asked (n=16/23, 70%) preferred to consider meaningful changes as a change in units (e.g., number of steps) versus percentages (e.g., a 25% improvement).

- "I think I would prefer to see it in units so that I wouldn't have to calculate what that is in my head. So, it would be much easier for me to have a – either know my goal or set a goal. If it were done in units, I would be able to clearly understand what my ability would be."
- "It's a much easier thing to just quickly be able to – if I'm using a step count or something, quickly be able to, like, look at and say, "Oh, this is – you know, difference between last week and this week is this."

Consistently, 10% or 25% changes in outcome were chosen as the smallest meaningful change across most vignettes, and participants were able to relate meaningful changes in DHT outcomes to potential broader impacts on daily life.

- "I would not shy away from activities that I know were going to require me to walk up and down stairs. I would not have to pre-plan routes, you know, to make sure that maybe, are there elevators, is there an escalator… some alternate means of me getting up and down at a location?... So to not have to consider all of those things, when leaving my home for something and going somewhere, that would be significant to me. '25%' would be fine. Anything more than that would be an absolute bonus."
- "I could stay up there on the floor dancing for a whole song [laughs], you know."

Participants had no difficulty selecting the measurement most important to them, with most individuals favouring time-based improvements (e.g., increasing the longest amount of time they are able to walk without taking a break).

CONCLUSION

This study indicates that participants can provide both qualitative and quantitative insights into meaningful change on DHT-based outcomes which may inform future measurement strategies. It is important that vignettes are comprehensible and relevant to the context of use, with baselines that can be tailored to each individual.