

USABILITY TESTING OF A NON-CONSUMER SMARTPHONE DEVICE FOR ePRO DATA COLLECTION

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INTRODUCTION

Non-consumer smartphone devices are used in a number of industries and provide important benefits in terms of global reach with fewer country-specific model variants and guaranteed model longevity. Popular consumer smartphones are superseded regularly and with little notice, which is undesirable for clinical trial studies where it is often desirable to use a common device across patients to collect patient reported data electronically.

An essential element of successful electronic patient reported outcome (ePRO) implementation is the usability of the hardware provided. This evaluation was conducted to assess the performance and essential usability properties of a non-consumer device, the Santok STK to determine its utility for home-based ePRO measure administration.

METHODS

1. In-house technical performance evaluation of the Santok STK was conducted using a high-end consumer smartphone as a benchmark. Parameters tested included: initial impression, performance, ease of use, screen quality, battery life and charging. Each evaluation item was summarized to a score on a 0-5 scale. Item scores were combined to give parameter scores for specific usability domains, and an overall score for each device.

2. External user testing of the Santok STK was conducted with ten participants who were recruited and consented (Ages: 13-77 years; Sex: 5F, 5M; Smartphone familiarity: Android: n = 4, iOS: n = 6; educational level: range).

Participants were asked to complete defined tasks, including turning on the device, opening an app, moving between display screens, answering questions on the app and checking internet and Bluetooth connectivity. They were individually observed and then interviewed on their experience of operating the device and using an associated ePRO app. An interview script was developed, tested and followed. Both quantitative and qualitative evaluations were made.

RESULTS

1. Technical performance evaluation.

- Time to load home screen, open and start the app from PIN entry was in line with expectations.
- Within-app screen loads were instantaneous.
- Device weight was in line with similar sized consumer smartphones.

Mean score met technical performance acceptance criteria; 3.8/5, vs high-end consumer device 4/5. Fig 1.

2. External user testing.

- Participants found most tasks easy and intuitive. The device performed particularly well on:
 - Perceived speed of screen loading. Score: 4.1/5.
 - Ease of use (score: 3.9/5), touchscreen sensitivity and accuracy. Score 4.2/5.
 - Screen clarity and brightness. Score 4.3/5.

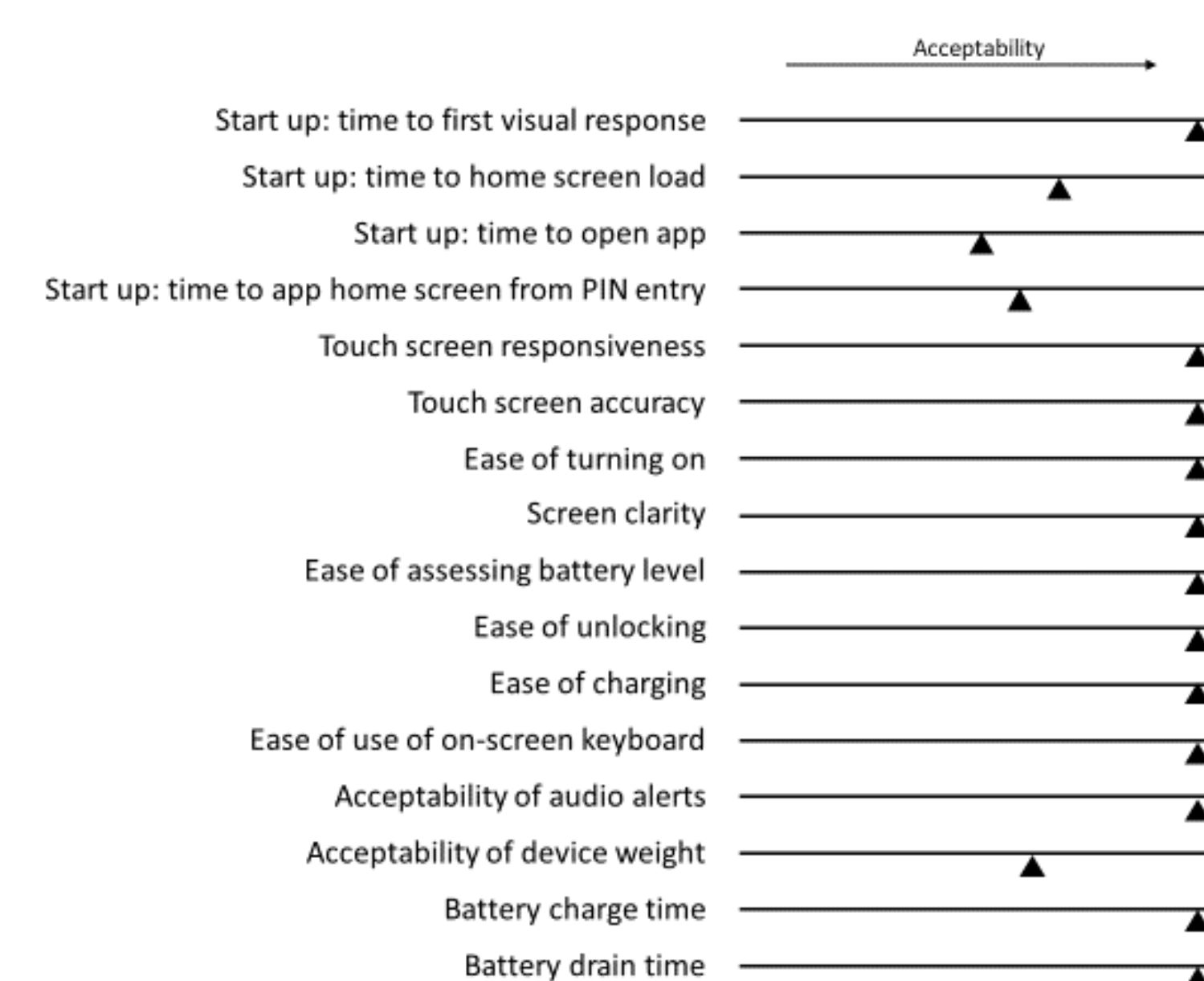
Mean score met usability acceptance criteria; 3.7/5. Fig 2.

CONCLUSIONS

Mobile technologies such as smartphones are increasingly being used to collect data from participants in clinical trials and non-consumer devices offer specific advantages over consumer alternatives. Ensuring that they offer acceptable performance and experience to clinical trial participants is an important component of solution usability, to ensure complete and compliant data collection in clinical trials.

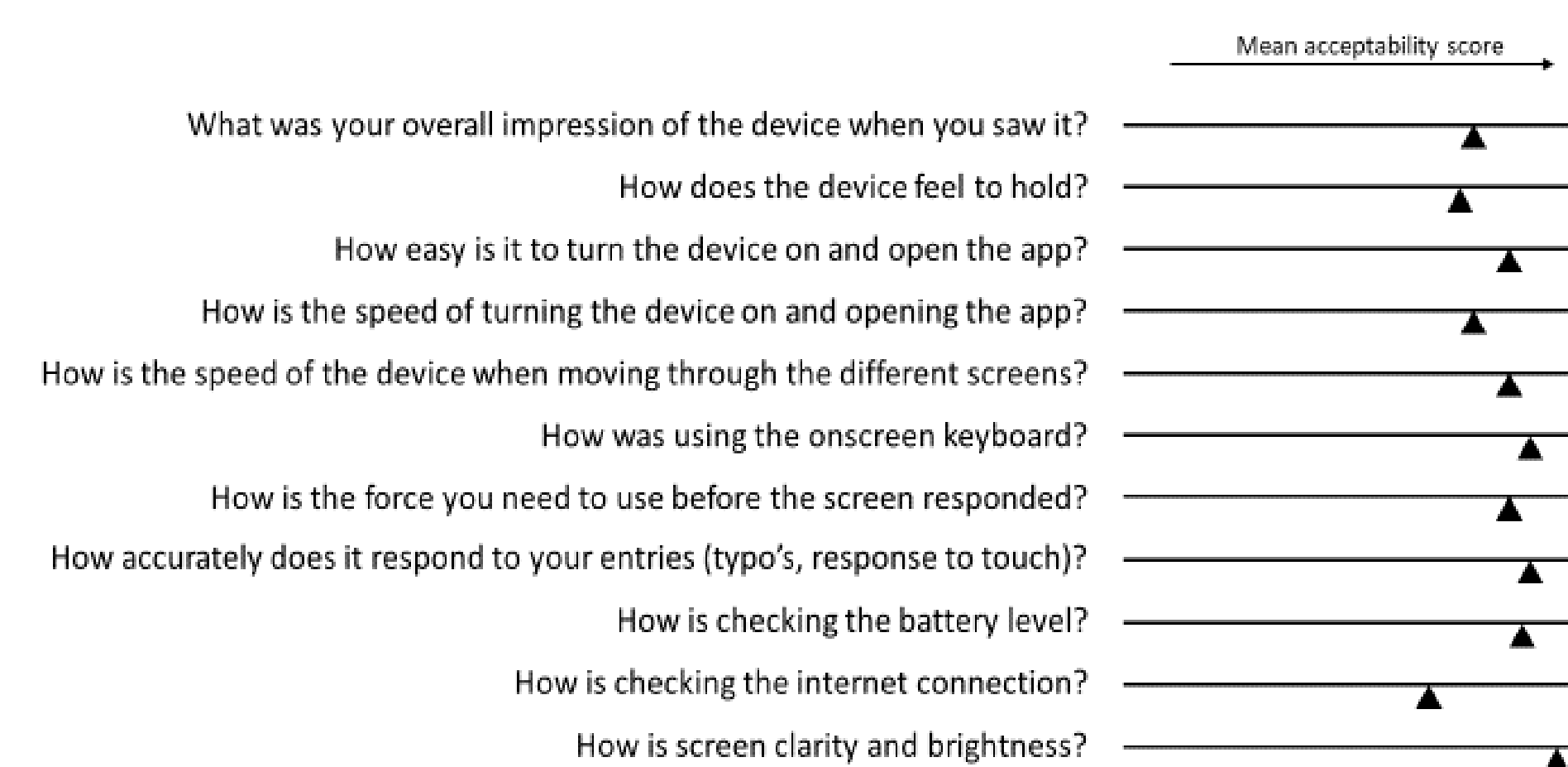
Internal performance and external user testing found the non-consumer Santok STK device to be a suitable and acceptable device to supply to clinical trial participants for collecting ePRO data.

FIGURE 1: IN-HOUSE PERFORMANCE TESTING



Parameter scores can be interpreted as : 0: no response, 1: very slow / very poor, 2: slow / poor, 3: acceptable, 4: quick / good, 5: Immediate / excellent.

FIGURE 2: EXTERNAL USER TESTING



Participant scores can be interpreted as : 0: impossible / unacceptable, 1: very poor, 2: poor, 3: acceptable, 4: good, 5: very good. good.