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**Running head:** Lung cancer risk prediction and smoking behavior

**Title:** Utilising lung cancer risk prediction models to promote smoking cessation: two randomised controlled trials

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## **TITLE**

Utilising lung cancer risk prediction models to promote smoking cessation: two randomised controlled trials

## **ABSTRACT**

### **Purpose**

The current project sought to examine whether delivery of lung cancer risk projections (calculated using the Liverpool Lung Project [LLP] risk model) predicted follow-up smoking status.

### **Design**

Two single-blinded randomised controlled trials.

### **Setting**

Stop Smoking Services in Liverpool (UK).

### **Subjects**

Baseline current smokers (N = 297) and baseline recent former smokers (N = 216) were recruited.

### **Intervention**

Participants allocated to intervention groups were provided with personalised lung cancer risk projections, calculated using the LLP risk model.

### **Measures**

Baseline and follow-up questionnaires explored socio-demographics, smoking behavior and lung cancer risk perceptions.

### **Analysis**

Bivariate analyses identified significant differences between randomisation groups and logistic regression models were developed to investigate the intervention effect on the outcome variables.

### **Results**

Lung cancer risk projections were not found to predict follow-up smoking status in the trial of baseline current smokers; however, they did predict follow-up smoking status in the trial of baseline recent former smokers (OR 1.91, 95% CI 1.03-3.55).

### **Conclusion**

The current study suggests that lung cancer risk projections may help maintain abstinence among individuals who have quit smoking, but the results did not provide evidence to suggest that lung cancer risk projections motivate current smokers to quit.

### **KEY WORDS**

Smoking cessation, cigarette smoking, smoking, cancer of lung, lung cancer, risk perception

### **INDEXING KEY WORDS**

1. Research
2. Intervention testing
3. Randomized trial

4. Behavioral
5. Health care
6. Smoking control
7. Behavior change
8. Adults
9. Geographic location

## **PURPOSE**

Lung cancer is the most commonly diagnosed cancer worldwide. In 2012, it was estimated that worldwide there were approximately 1.8 million new lung cancer cases and 1.6 million lung cancer mortalities.<sup>1</sup> In the UK alone, approximately 86% of lung cancer cases have been attributed to tobacco smoking.<sup>2</sup> Despite smoking cessation being identified as one of the most effective strategies in reducing lung cancer incidence,<sup>3</sup> smoking cessation success remains at a mere 1-5% of smokers each year.<sup>4</sup> Poor smoking cessation success rates demonstrate the need for new, innovative and effective tobacco control ventures.

One of the most promising approaches to smoking cessation interventions for entire populations are tailored risk communications.<sup>5</sup> A recent Cochrane review suggested that personalised risk information was associated with increased informed choice, increased knowledge, and more accurate risk perceptions.<sup>6</sup> Furthermore, although relatively few studies have identified a causal association between generic risk communication and behaviour change, the importance of tailoring risk communications to the individual characteristics of targets has previously been emphasised.<sup>7</sup>

Lung cancer risk prediction models are statistical models that estimate the probability of developing lung cancer within a given time period; such models consider and incorporate various risk factors. Lung cancer risk prediction models may offer a new opportunity for the delivery of tailored risk communications, as previous research has failed to explore the application of lung cancer risk prediction models in the context of smoking cessation. The Liverpool Lung Project (LLP) developed a lung cancer risk prediction model for predicting five-year risk, based on 579 lung cancer cases and 1,157 age and sex matched population-based controls.<sup>8</sup> Various risk factors were incorporated into the model including, age, sex, smoking history, occupational exposure to asbestos, prior diagnosis of pneumonia, prior diagnosis of malignant tumour (except lung cancer), and family history of lung cancer. The model demonstrates good discrimination between cases and controls, with a reported area under the curve (AUC) of 0.71.<sup>8</sup> Furthermore, the model has been validated within three independent populations (UK, Europe, and North America)<sup>9</sup> and has been utilised to recruit high risk individuals into the UK Lung Cancer Screening Trial (UKLS).<sup>10</sup>

The data within this article derive from two pragmatic randomised controlled trials (RCTs), which examined the feasibility and efficacy of providing personalised lung cancer risk projections to current and recent former smokers, with the intention of enhancing smoking cessation rates at six-month follow-up. The current project sought to achieve this objective by delivering lung cancer risk projections, calculated using the LLP risk model among individuals recruited via a local Stop Smoking Services (SSS), in North West England. SSS typically aim to support smokers within local communities to quit by providing a range of pharmacotherapy products and behavioural therapies.<sup>11</sup> Secondly, the effect of lung cancer risk projections on lung cancer risk perceptions was also explored, in order to provide further insight regarding the relationships between risk communication, risk perception, and smoking behavior. If lung

cancer risk projections using lung cancer risk prediction models do predict follow-up smoking status, this has important implications; delivery of lung cancer risk projections could reduce the burden of smoking-related disease and in turn, smoking-related mortalities.

## **METHODS**

### **Sample**

All participants were consented via community drop-in sessions delivered by a SSS in North West England, between November 2013 and June 2014. The drop-in sessions enabled service users to attend at any point within a given time period and the number of service users attended sessions ranged greatly (0-30). It should be noted that the number of occasions that participants had attended SSS drop-in sessions previously was not reported. Participants were aged 18-60 years and participants were excluded from the project if they had previously been diagnosed with lung cancer. The first trial incorporated a sample of current smokers (i.e. individuals who had smoked within the previous week) ( $n = 302$ ), however, at six-month follow-up five participants were either deceased or relocated to an untraceable address, resulting in a final sample of 297 participants (see Figure 1). The second trial incorporated a sample of recent former smokers (i.e. those who had already stopped smoking and had not smoked at all in the 7 days prior to recruitment) ( $n = 219$ ), although at six-month follow-up three participants were either deceased or relocated to an untraceable address, resulting in a final sample of 216 participants (see Figure 1); at baseline, the median number of days abstinent in the second trial (of recent former smokers) was 39.0 days (IQR = 21.0-75.0), with a minimum and maximum reported number of seven and 600 days abstinence, respectively (although only four participants reported abstinence for over one year).

### **Design and procedure**



Ethical approval was acquired for the project via Liverpool Central National Research Ethics Service Committee. Participants were made aware that they could withdraw from the study at any time, data were anonymised, strict confidentiality guidelines were adhered to, and participants were aware that the results derived from the data they provided may be published in a scientific journal.

The project entailed the implementation of two RCTs. The first RCT consisted of baseline current smokers and the second RCT consisted of baseline recent former smokers; the trials were undertaken in parallel. Although participants were designated to a trial based on smoking status, both trials followed the same design and procedure, which will now be described and is illustrated in Figure 1.

Upon arriving at a community drop-in session delivered by a local SSS, service users were provided with a participant information sheet (PIS). Following service users' consultations with a smoking cessation advisor, service users were introduced to a researcher by the smoking cessation advisor, in order to avoid influencing service users' decisions to participate. Service users were offered the opportunity to discuss trial participation in greater detail, privately but still within the drop-in session locality. Service users who were happy to participate were requested to sign a consent form and complete a baseline questionnaire. The researcher offered to complete the questionnaire with all participants and pens were provided for those who wished to complete the questionnaire without the support of the researcher.

Following completion of the baseline questionnaire, participants were stratified into one of the two trials, dictated by the participant's baseline smoking status (i.e. baseline current smokers or baseline recent former smokers); smoking status classification is detailed later in the paper.

Within the respective trial, participants were subsequently randomised into one of two groups: (1) the control group, or; (2) the intervention group. Randomisation software was utilised to allocate participants on a 1:1 ratio (via the URL, <http://www.randomization.com/>). Participants were blinded to randomisation group allocation; participants in both intervention and control arms were informed that they would receive lung cancer risk information but the nature of the information (i.e. generic or personalised) was not disclosed until debriefing.

Participants allocated to the control groups for both trials were provided with simplistic, generic smoking risk communication in the form of a pamphlet. The generic pamphlet simply stated the association between smoking and lung cancer and highlighted that quitting smoking was the best thing to do to avoid many serious diseases, including lung cancer. Participants allocated to intervention groups for both trials were provided with the same generic pamphlet as above but additionally, they received the intervention (detailed later in this paper).

Participants were informed that they would be contacted at six-months to ascertain outcome variables. Six-month follow-up questionnaires were predominantly undertaken by telephone. Telephone calls were attempted three times, at different times of the day, before a paper questionnaire was dispatched to a participant's address with a stamped addressed envelope and letter, requesting completion. Follow-up responses relied upon participants' goodwill, as no financial (or other) incentives were used. At six-month follow-up, participants were debriefed regarding randomisation blinding and study aims. Participants allocated to the control arm were offered the intervention upon completing the follow-up questionnaire and being debriefed regarding blinding.

## **Measures**

Questionnaires were completed at baseline and at six-month follow-up. Baseline questionnaire measures included variables pertaining to socio-demographics, lung cancer risk factor exposure, smoking behavior, and lung cancer risk perceptions. Age, gender, ethnicity, marital status, highest educational attainment, and socio-economic status were ascertained. The measures for ethnicity and highest educational attainment have been previously adopted.<sup>12</sup> The measure for marital status was based on the measure used as part of the LLP<sup>8</sup> whilst socio-economic status was ascertained using English Index of Multiple Deprivation (IMD) ranks. IMD is a robust index, which uses 38 separate indicators of deprivation.<sup>13</sup> IMD information was obtained using a website developed by Mimas at the University of Manchester<sup>14</sup> and the output was reported as ranks within five quintiles, as described elsewhere.<sup>15</sup> Socio-economic status and marital status variable levels were, however, subsequently transformed, due to some low cell frequencies. The transformed variable for socio-economic status consisted of: (1) Most deprived (Most deprived), and; (2) Least deprived (Above average deprivation, Average deprivation, Below average deprivation, Least deprived). The transformed variable for marital status consisted of: (1) Other (Divorced, Separated, Widowed and Other); (2) Single (Single), and; (3) Married or living together (Married, Living together).

Data were also collected pertaining to additional lung cancer risk factor exposure, as guided by the LLP risk model;<sup>8</sup> details regarding occupational exposure to asbestos, prior diagnosis of pneumonia, prior diagnosis of malignant tumour (except lung cancer), and family history of lung cancer were all established as part of the baseline questionnaire. Although these four variables were not of relevance to trial data analyses, they were required to calculate lung cancer risk projections.

Smoking behavior was also investigated. Smoking status was measured at baseline using 7-day point prevalence (PP). 7-day PP is commonly used in smoking cessation trials and can be advantageous, as it captures the dynamic, real-life process of smoking cessation.<sup>16</sup> Age started smoking, whether or not the participant lived with another smoker, and cigarettes per day (retrospectively where applicable) were recorded. Nicotine dependence was measured using the Fagerström Test for Nicotine Dependence (FTND).<sup>17</sup> FTND scores were calculated based on six items and scores ranged from 0-10; low to high dependency. Baseline quit duration (in days) was also calculated among those in the second trial (i.e. baseline recent former smokers).

Several lung cancer risk perceptions were additionally measured. Measures for perceived personal lung cancer risk, perceived lung cancer risk of the average smoker, and perceived relative risk of lung cancer were developed based on previously applied measures,<sup>18</sup> whilst the measures for lung cancer worry and perceived lung cancer survival were adapted from a prior study.<sup>19</sup>

The six-month follow-up questionnaire entailed several repeated measures, including smoking status (using 7-day PP), quit duration, and all aforementioned lung cancer risk perceptions, with the exception of perceived lung cancer survival, as this measure was not anticipated to be an outcome. Furthermore, an intention-to-treat approach was adopted at follow-up, which entailed classifying participants lost to follow-up as current smokers (with the exception of those who had died and those documented as having moved to an untraceable address).<sup>20</sup>

## **Intervention**

The researcher delivered the intervention to participants individually, following completion of the baseline questionnaire. The intervention was delivered immediately after participants completed the baseline questionnaire and took approximately 10 minutes to deliver.

The researcher brought a laptop computer to all drop-in sessions. A Microsoft Access database was saved on the laptop computer. The database incorporated formulae associated with the LLP risk model (see elsewhere) <sup>8</sup> and included a user interface, enabling the researcher to input data collected from a participant's questionnaire to ascertain a participant's risk profile. The database was able to provide an individual risk profile, using the LLP risk model formulae, by inputting a participant's age, gender, smoking duration, occupational exposure to asbestos, prior diagnosis of pneumonia, prior diagnosis of malignant tumour (except lung cancer), and family history of lung cancer. The database was able to incorporate all of these risk factors and estimate projected five-year lung cancer risk at the age of 70 years old.

Lung cancer risk at 70 years was estimated for all participants in the intervention groups and estimates were provided for two hypothetical circumstances: (1) continued smoking from present until the 70 years, and; (2) smoking cessation from present until the 70 years. Providing two hypothetical estimates enabled the researcher to demonstrate the benefit of stopping smoking, compared to continuing to smoke. For example, a 43 year old male, with 33 years smoking duration, a previous diagnosis of pneumonia, no previous malignancies, no family history of lung cancer, and no previous asbestos exposure, demonstrated a 12% projected five-year lung cancer risk at 70 years if they continued to smoke, whereas, their projected five year lung cancer risk at 70 years was only 5% if the individual stopped smoking at the age of 43 years.

Lung cancer risk projections were detailed verbally to participants, including a brief explanation as to which risk factors informed the projections, the meaning of projected five-year lung cancer risk at 70 years old, the projected difference between stopping and continuing to smoke, and a plain English summary of the LLP risk model. Participants were also offered the opportunity to ask questions about lung cancer risk projections. Furthermore, lung cancer risk projections were also presented in a pamphlet. The researcher calculated risk using the Microsoft Access database and discussed the resulting risk projections, with the aid of the pamphlet.

The pamphlet stated “If you were to continue smoking, your estimated risk of getting lung cancer between the ages of 70 and 74 years old will be [...] % BUT if you quit smoking from now on, your estimated risk of getting lung cancer between the ages of 70 and 74 years old will be reduced to [...] %”. Beside each of the two estimations was an illustration that included 100 squares. The appropriate number of squares were coloured red by the researcher to represent the percentage of risk for each of the estimations. The pamphlet also provided background on the LLP risk model, highlighted that the projections were based on the information provided by the participant and that if this information differed from now until the age at which risk is projected, the results may also differ. Lastly, the pamphlet provided contact details if the participant wished to find out more about the LLP risk model or the information provided. Participants were provided with the pamphlet to keep.

## **Analysis**

Both trial datasets were analysed using the same analytical approach. Bivariate tests were undertaken to explore differences in baseline participant characteristics across randomisation groups. Relationships were ascertained using  $\chi^2$  test or Fisher’s exact test as appropriate for

categorical variables. For continuous variables, Mann Whitney U-tests were utilised to identify significant differences between variable levels. Logistic regression analyses were subsequently conducted to explore the effect of the intervention on follow-up smoking status, perceived personal lung cancer risk, perceived average smoker lung cancer risk, perceived relative risk of lung cancer, and lung cancer worry. Purposeful selection of covariates and potential confounders were included as per previous guidance (i.e. the logistic regression models adjusted for variables significant at the level of 25%).<sup>21</sup> All analyses were performed using IBM-SPSS® statistical software.<sup>22</sup>

It should be noted that since there is a paucity of research regarding the provision of personalised lung cancer risk projections, the anticipated effect of the intervention was uncertain. A power calculation was undertaken to determine the required sample size for the trial considering baseline current smokers. The calculation indicated that a sample size consisting of 785 baseline current smokers (randomised on a 1:1 basis) was required to detect a 10% difference in smoking cessation, considering 80% power for a 5% two-sided type 1 error, as guided by the literature.<sup>23</sup>

## **RESULTS**

### **Trial 1: Baseline current smokers**

The first trial explored the intervention effect among baseline current smokers. The median age for the sample overall was 42.0 years old (IQR = 31.0-51.0) and most baseline current smokers were female ( $n = 177$ , 59.6%), White ( $n = 271$ , 92.2%), and Single ( $n = 157$ , 53.2%). Participants marginally tended to have higher qualifications (i.e. achieving qualifications beyond General Certificate of Secondary Education level) ( $n = 154$ , 53.1%), although the vast

majority were classified within the most deprived quintile with regards to socio-economic status ( $n = 255$ , 86.1%). Table 1 displays the distribution of baseline participant characteristics across randomisation groups in respect to the first trial.

A number of bivariate tests were undertaken to examine relationships between randomisation groups and the aforementioned baseline participant characteristics (see Table 1). Age ( $p = 0.154$ ), socio-economic status ( $p = 0.003$ ), and perceived relative risk of lung cancer ( $p = 0.024$ ) were adjusted throughout the logistic regression analyses, as these variables were significant at the level of 25%.<sup>21</sup> There were no significant associations between randomisation group and gender, ethnicity, marital status, highest educational attainment, age started smoking, living with another smoker, FTND, cigarettes per day, perceived personal lung cancer risk, perceived average smoker lung cancer risk, lung cancer worry, and perceived lung cancer survival.

Logistic regression analyses were conducted to explore the intervention effect on six-month follow-up outcome variables. The intervention failed to predict any of the six-month follow-up outcome variables, including 7-day PP (smoking status) ( $p = 0.658$ ), perceived personal lung cancer risk ( $p = 0.785$ ), perceived average smoker lung cancer risk ( $p = 0.950$ ), perceived relative risk of lung cancer ( $p = 0.580$ ) and lung cancer worry ( $p = 0.455$ ).

### **Trial 2: Baseline recent former smokers**

The second trial explored the intervention effect among baseline recent former smokers. The median age was 44.0 years old (IQR = 37.0-52.8). The majority of baseline recent former smokers were female ( $n = 118$ , 54.6%) and White ( $n = 197$ , 91.6%), whilst Single was the most frequently reported marital status ( $n = 92$ , 43.0%). Participants marginally tended to have lower qualifications (i.e. achieving General Certificate of Secondary Education level or below) ( $n =$



114, 53.0%), and again, the vast majority were classified within the most deprived quintile in relation to socio-economic status ( $n = 182$ , 84.3%).

Several bivariate analyses were undertaken to examine relationships between randomisation group and baseline participant characteristics (see Table 2). Age ( $p = 0.122$ ), gender ( $p = 0.243$ ), ethnicity ( $p = 0.241$ ), marital status ( $p = 0.178$ ), highest educational attainment ( $p = 0.001$ ) and quit duration ( $p = 0.156$ ) were adjusted throughout the logistic regression analyses, as these variables were significant at the level of 25%.<sup>21</sup> There were no significant associations between randomisation group and socio-economic status, age started smoking, living with another smoker, FTND, cigarettes per day, perceived personal lung cancer risk, perceived average smoker lung cancer risk, perceived relative risk of lung cancer, lung cancer worry, and perceived lung cancer survival.

Logistic regression analyses were subsequently conducted to explore the intervention effect on six-month follow-up outcome variables (see Table 3). The intervention was found to significantly predict 7-day PP (smoking status) at six months (OR 1.91 95% CI 1.03-3.55); however, the intervention failed to predict follow-up perceived personal lung cancer risk ( $p = 0.711$ ), perceived average smoker lung cancer risk ( $p = 0.567$ ), perceived relative risk of lung cancer ( $p = 0.874$ ) and lung cancer worry ( $p = 0.869$ ). Thus, the findings suggest that lung cancer risk projections may promote abstinence among individuals who have recently quit smoking, but the results suggest they do not motivate current smokers to quit.

## **DISCUSSION**

Previous research has suggested that tailored risk communications provide one of the most promising approaches to smoking cessation interventions for entire populations;<sup>5</sup> suggesting

that the application of lung cancer risk prediction models in the context of smoking cessation could prove highly beneficial in promoting smoking cessation success rates. The current study identified that lung cancer risk projections were associated with follow-up smoking status among baseline recent former smokers, but not among baseline current smokers. To our knowledge, this is the first study to evaluate the utility of a lung cancer risk prediction model in the context of smoking cessation. Our results demonstrate that the output produced from lung cancer risk prediction models (such as the LLP risk model<sup>8</sup>) can be adapted to deliver tailored lung cancer risk projections to the general public.

Behavior change theory may provide some explanation as to why a significant effect was identified in the trial of baseline recent former smokers but not in the trial of baseline current smokers, as well as considering why provision of lung cancer risk projections failed to predict follow-up lung cancer risk perceptions in either of the trials. One of the most dominant models of behavior change that has been applied extensively to smoking behavior,<sup>24-26</sup> is the Transtheoretical Model of Change (or TTM).<sup>27</sup> The TTM proposes and systematically incorporates several concepts considered influential to behavior change, including the stages of change and the processes of change.<sup>27,28</sup> Furthermore, the TTM stipulates that specific processes of change, such as “reinforcement management” may be more applicable among individuals progressing from the active stage of change to the maintenance stage of change (i.e. baseline recent former smokers), whereas, processes of change, such as “self-liberation” may be more applicable to current smokers progressing from the preparation stage of change to the action stage of change (i.e. baseline current smokers). This might suggest that lung cancer risk projections may provide recent former smokers with a reinforcing message pertaining to behavior change, although this message may be less applicable to current smokers preparing to quit smoking. Further research is required to fully understand this mechanism.

The study has some limitations. Firstly, it was not possible to recruit the optimal number of smokers in each of the trials and achievement of abstinence was substantially lower than anticipated for the power calculation regarding the trial of baseline current smokers (actual 21%, compared to an expected 26%); we therefore had insufficient statistical power to conclude superiority of the intervention. A larger trial or extension to the current project would certainly be beneficial to explore whether the results are replicable. Secondly, the current project relied on self-reports with regards to smoking status. Future studies that explore the impact of tailored smoking risk communication should always endeavour to biochemically verify self-reported smoking status.<sup>20</sup> Despite this, the value of self-reported smoking status should not be underestimated; one review surmised that sensitivity means and specificity means of self-reported smoking status were both high when compared with biochemical indices.<sup>29</sup>

It should also be noted that 7-day PP was used to measure smoking status at baseline and six-month follow-up; a measure that has been argued to be highly advantageous, enabling the dynamic, real-life process of smoking cessation to be captured.<sup>16</sup> Some researchers, however, recommend the use of prolonged abstinence (i.e. self-reported continuous abstinence) in addition to point prevalence, to further enhance reliability.<sup>30</sup> Future research might benefit from inclusion of both measures to improve confidence in the result that abstinence was maintained throughout the follow-up period. Lastly, a clustered RCT design may have also been beneficial. Although attempts were made to avoid contamination of randomisation blinding by delivering the intervention to participants in private, some participants may have inadvertently disclosed their randomisation group in contact with service users following the SSS drop-in session; it should be noted, however, that this was not apparent.

In terms of behavior change theory, the current study supports the notion that stage-based interventions may be particularly beneficial in promoting long-term smoking cessation; a recent Cochrane review summarised that the effectiveness of stage-based interventions for smoking cessation remains unclear.<sup>26</sup> If a future, larger trial is able to replicate the current study findings, a cost-benefit analysis would be beneficial to consider delivery of lung cancer risk projections within Stop Smoking Services on a wider scale. Stop Smoking Services quit rates have remained fairly constant within recent years in England;<sup>31</sup> therefore, new, innovative and effective interventions would certainly be welcomed nationally and undoubtedly, internationally. Furthermore, lung cancer risk projections (using the LLP risk model) can be obtained using a simple database, thus, enabling non-clinicians to communicate lung cancer risk with minimal training. It may also be feasible to deliver lung cancer risk projections in alternate settings to local Stop Smoking Services, such as General Practitioner (GP) surgeries and hospital settings; however, further research is required to explore the effect of providing lung cancer risk projections among other smoking populations.

The current study showed that provision of lung cancer risk projections predicted six-month follow-up smoking status among baseline recent former smokers, but not among baseline current smokers. The delivery of lung cancer risk projections, using risk models such as the LLP risk model may improve long-term smoking cessation rates, which could subsequently reduce the burden of smoking-related diseases and mortalities; further research is required.

## **SO WHAT?**

### **What is already known on this topic?**

Smoking cessation is one of the most effective strategies in reducing lung cancer incidence and tailored risk communications have been identified as one of the most promising approaches to smoking cessation. Lung cancer risk prediction models may offer a new opportunity for the delivery of tailored risk communications.

### **What does this article add?**

To our knowledge, this is the first study to explore the application of a lung cancer risk prediction model in the context of smoking cessation. The findings suggest that lung cancer risk projections may promote abstinence among individuals who have recently quit smoking, but they do not motivate smokers to quit.

### **What are the implications for health promotion practice or research?**

The delivery of risk communications using lung cancer risk prediction models may greatly improve long-term smoking cessation rates, which may in turn reduce the burden of smoking-related diseases and mortalities.

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## **FIGURE CAPTIONS**

**Figure 1.** Flow of participants through the two project trials