



Applying the Transtheoretical Model to evaluate the effect of a call–recall program in enhancing Pap smear practice: A cluster randomized trial^{☆,☆☆}



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ABSTRACT

Objective. The objective of this study was to evaluate the effect of a call–recall approach in enhancing Pap smear practice by changes of motivation stage among non-compliant women.

Methods. A cluster randomized controlled trial with parallel and un-blinded design was conducted between January and November 2010 in 40 public secondary schools in Malaysia among 403 female teachers who never or infrequently attended for a Pap test. A cluster randomization was applied in assigning schools to both groups. An intervention group received an invitation and reminder (call–recall program) for a Pap test (20 schools with 201 participants), while the control group received usual care from the existing cervical screening program (20 schools with 202 participants). Multivariate logistic regression was performed to determine the effect of the intervention program on the action stage (Pap smear uptake) at 24 weeks.

Results. In both groups, pre-contemplation stage was found as the highest proportion of changes in stages. At 24 weeks, an intervention group showed two times more in the action stage than control group (adjusted odds ratio 2.44, 95% CI 1.29–4.62).

Conclusion. The positive effect of a call–recall approach in motivating women to change the behavior of screening practice should be appreciated by policy makers and health care providers in developing countries as an intervention to enhance Pap smear uptake.

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Introduction

The Papanicolaou test has been recognized as a primary screening tool for the early detection of cervical cancer since the 1940s, implemented worldwide through either opportunistic or organized approaches (Nygård, 2011; Papanicolaou, 1948). In opportunistic screening, the service is provided to women who request it or who attend a health facility. This approach has been employed in Malaysia since 1960s. Yet, cervical cancer ranked as the second commonest cancer in Malaysian women with an incidence rate of 12.2 per 100,000 in 2006 and 80% of patients presented late (Chye et al., 2008; Omar et al., 2006; Othman et al., 2009). In an organized program, women are regularly invited for screening tests, which have been practiced in many developed and few middle-income countries in Latin America and Eastern Europe.

Thus, these countries experience lower cervical cancer burden (Gakidou et al., 2008; Miles et al., 2004).

To our knowledge none of the studies have evaluated the impact of a call–recall screening practice on changes in the stages of cervical screening behavior among women. Hence, a cluster randomized trial was undertaken to determine this. The trial was chosen for practical reasons and to prevent contamination by preferences of teachers.

Methods

Trial design and participants

The study was a two armed, parallel group, un-blinded, and cluster randomized controlled trial. The clusters were national secondary schools with 84 schools in Kuala Lumpur which divided into four zones with an average of 20 schools per zone. 10 schools were selected at random from each of these zones and randomized (1:1) to the intervention or non-intervention arms of the trial. Female secondary teachers who were either naïve to Pap smear or had their last test more than three years were invited to participate in the study (n = 403).

Sample size

Sample size was calculated using OpenEpi (Dean et al., 2012); based on a 1:1 ratio of case to control participants, the study would need approximately

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200 participants (inclusive of an additional 20% to account for non-respondents and design effect of two (Adamchak et al., 2000; World Health Organization, 2012) without cluster effect) in the intervention and comparator arms to have over 80% power at the 95% confidence level (alpha 0.05, two sided) to detect an effect size of 31% (Eaker et al., 2004).

Data collection

Data were collected from January to November 2010. A pre-tested self-administered baseline questionnaire was sent to all participants who fulfilled the inclusion criteria and consented to participate in the study. The baseline survey covered five areas: i) demographic and socioeconomic factors; ii) reproductive history; iii) healthy lifestyle or risk behavior; iv) attitudes and beliefs of cervical screening practice, and v) stages of cervical screening behavior change by applying the Transtheoretical Model (TTM) (Glanz et al., 1997; Prochaska and DiClemente, 1983). A post-intervention questionnaire was administered at 24 weeks where the information on stages of cervical screening behavior change was collected as main outcome.

Randomization

Using a computer generated simple randomization method in SPSSv15, each of the 40 public secondary schools which had agreed to participate was randomized into either the intervention (n=20) or control (n=20) groups whereby all teachers from the same school (cluster) were assigned to the same group. Randomization was revealed after recruitment of the final school to ensure concealment of allocation (Fig. 1).

Intervention

A call–recall program was introduced to the intervention group, which includes a personal invitation letter with an information pamphlet of cervical cancer screening, and followed by a telephone reminder with counseling after four weeks that was performed once per participant. The control group received usual care from the existing program.

Statistical analysis

Baseline characteristics were compared using a *t*-test for continuous variables and a chi-squared test for categorical data. Multivariate logistic regression was applied to calculate odds ratios (ORs) and 95% confidence intervals (CIs) for the effect of the intervention on the action stage (Pap smear uptake). Variables from univariate analysis (irrespective of the intervention status) which had a *p*-value ≤ 0.25 were selected for the multivariate model. Collinearity among the variables in the multivariate model was checked and determined absent. The value from the Hosmer–Lemeshow goodness-of-fit test of the multivariate model was 3.74 (df=8, *p*-value=0.880) indicating a well calibrated model. SPSSv15 was used for all analyses.

Results

Twenty secondary schools were allocated to receive the intervention (n=201 eligible participants) and 20 schools (n=202 eligible participants) were assigned to the standard (opportunistic) cervical screening arm. Both groups were followed up after a period of 24 weeks, at which point subsequent uptake of Pap examination (action stage) was examined. Two participants from the intervention arm (both of whom were un-contactable) and three from the control arm (one un-contactable, one refused participation and one could not participate due to medical leave) were lost to follow-up, leaving 20 schools with 199 participants in each arm for analysis. By baseline characteristics, both groups were equally comparable to each other (Table 1).

The highest proportion of changes in stages in both groups was noted among those that belong to pre-contemplation stage, with slightly higher in the intervention group (Table 2). Chi-square test value of 19.893 showed that in all the stages, there was a significant difference in the changes of stage at 24 weeks in both groups (*p*-value<0.05).

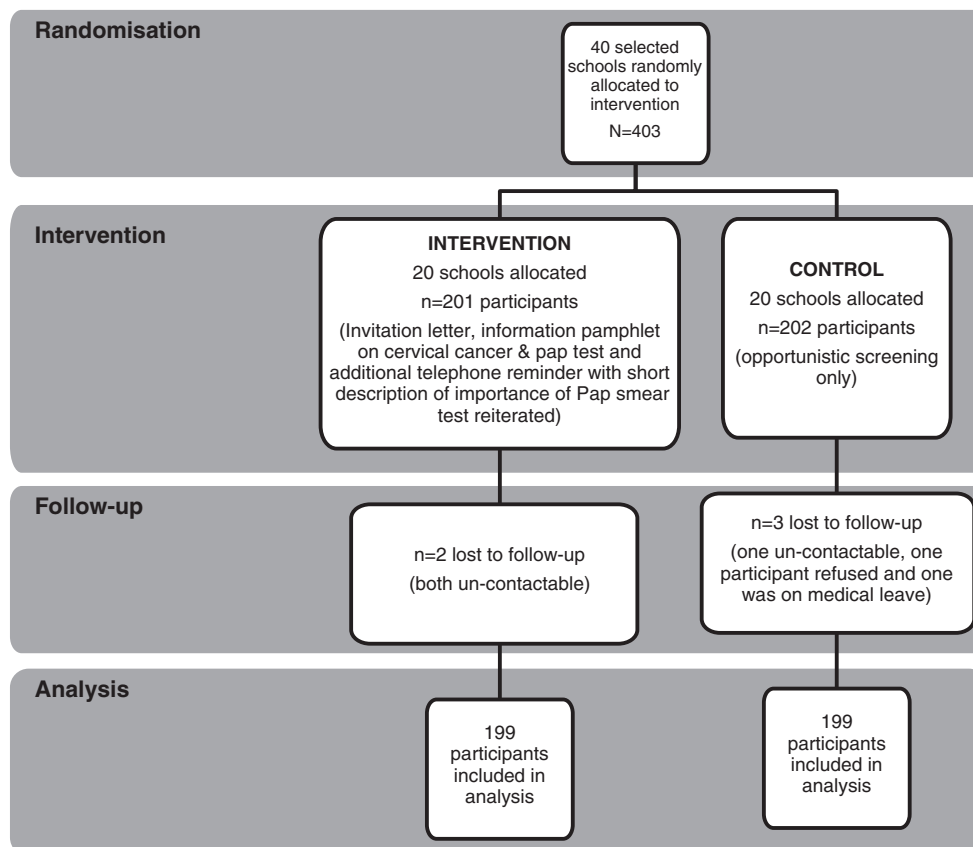


Fig. 1. Flow of participants in the intervention and control arm (Malaysia, 2010).

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