ENHANCEMENT OF LEARNING ON SAMPLE SIZE CALCULATION WITH A SMARTPHONE APPLICATION: A CLUSTER-RANDOMIZED CONTROLLED TRIAL

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Abstract. Sample size determination usually is taught based on theory and is difficult to understand. Using a smartphone application to teach sample size calculation ought to be more attractive to students than using lectures only. This study compared levels of understanding of sample size calculations for research studies between participants attending a lecture only versus lecture combined with using a smartphone application to calculate sample sizes, to explore factors affecting level of post-test score after training sample size calculation, and to investigate participants' attitude toward a sample size application. A cluster-randomized controlled trial involving a number of health institutes in Thailand was carried out from October 2014 to March 2015. A total of 673 professional participants were enrolled and randomly allocated to one of two groups, namely, 341 participants in 10 workshops to control group and 332 participants in 9 workshops to intervention group. Lectures on sample size calculation were given in the control group, while lectures using a smartphone application were supplied to the test group. Participants in the intervention group had better learning of sample size calculation (2.7 points out of maximnum 10 points, 95% CI: 24 - 2.9) than the participants in the control group (1.6 points, 95% CI: 1.4 - 1.8). Participants doing research projects had a higher post-test score than those who did not have a plan to conduct research projects (0.9 point, 95% CI: 0.5 - 1.4). The majority of the participants had a positive attitude towards the use of smartphone application for learning sample size calculation.

Keywords: learning, sample size calculation, smartphone application, teaching

INTRODUCTION

An appropriate sample size enables an investigator to detect a real effect with sufficient precision and minimal cost (Wittes, 2002; Lan and Lian, 2010; Sathian *et al*, 2010). However, investigators often have difficulty in selecting a suitable formula for their projects because there are many formulae that can be applied depending on study design and type of data (Noordzij *et al*, 2010). Thus, sample size calculation is too difficult to understand by researchers who do not have

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prior knowledge of statistics.

Lectures with note-taking approach constitute a traditional method for teaching sample size calculation. Using this approach, learners feel complexed and bored (Ali *et al*, 2011). Several studies proposed many approaches to reduce these barriers in teaching statistics using technology as a supplement tool, *viz*, computer assisted instruction (Basturk, 2005; Larwin and Larwin, 2011), use of statistical software or spreadsheet (Mills, 2002; Nash, 2008), and internet or web-based learning (Mills, 2002; Justham and Timmons, 2005; González *et al*, 2010; Wang *et al*, 2011; Tawil *et al*, 2012). However, those teaching approaches require a personal computer or laptop and an internet connection. Learners must have some level of computer literacy and skill to learn how to use the software before they can obtain the desired knowledge.

In recent years, mobile devices, which are more widely available than computers/laptops, have played an increasing role in education (Sung *et al*, 2016). A research synthesis of integrated mobile devices in teaching in various fields found that using mobile devices in education is better than using desktop computers or not using mobile devices (Sung *et al*, 2016). Use of a smartphone application (app) thus provides an alternative tool for teaching sample size calculation as most investigators and students currently have their own personal smartphones.

Health professionals and students in health sciences often need to conduct their research projects and to determine the appropriate number of participants for their studies. Health researchers often are adverse to perform sample size calculation (Pye *et al*, 2016), and recalculate the sample size after consulting advisers, experts, and statisticians (Deutsch *et al*, 2007). Thus, a sample size calculation app on a smart device might be a welcome tool to allow pre-determination of required sample size.

There is a lack of supporting evidence on whether a smartphone app improves investigators' or students' understanding of the theory related to sample size, factors influencing understanding of sample size calculation, and attitudes towards using smartphone app for calculating sample size. Therefore, this study was undertaken to compare level of understanding on sample size calculation after attending a workshop using lecture format only compared with lectures supplemented with a smartphone app ("n4Studies") to teach sample size calculation for research studies. In addition, we documented factors influencing the level of post-test score following the training workshop and investigated the participant's attitude towards using smartphone app. The findings will have implications on statistics education as well as on future smartphone app development.

MATERIALS AND METHODS

Study setting and design

The study was conducted in four provinces (Bangkok, Chiang Mai, Khon Kaen and Songkhla) of Thailand during October 2014 to March 2015. Nineteen workshops for teaching and practising sample size calculations were conducted in research training programs in six universities, three hospitals and one health office. Participants attending these workshops were health professionals including physicians, nurses, researchers, lecturers, public health officers, medical residents, and students. The number of participants for the study was calculated based on comparison of average knowledge scores

(Lake *et al*, 2002; Wittes, 2002), which took into account an intraclass correlation coefficient of 0.05, an average cluster size of 35, a standard deviation of 1, and a power of 80% to detect a difference of 0.35 in post-test scores between two groups with a significance level of 0.05. With these parameters, a sample size of 349 participants in each group is required.

The research design was a cluster-randomized controlled trial. Nineteen workshops were used as units of assignments rather than participants. After enrolment in the study, workshops were allocated to either control or intervention group (Fig 1). Both groups were given a pre-test assessment at the beginning. The control group was assessed on their theoretical knowledge on sample size calculation immediately after the lecture. The intervention group was assessed on the same content but after practical session. Finally, before the workshop was closed, attitudes of the participants towards smartphone app were assessed by a self-completed questionnaire.

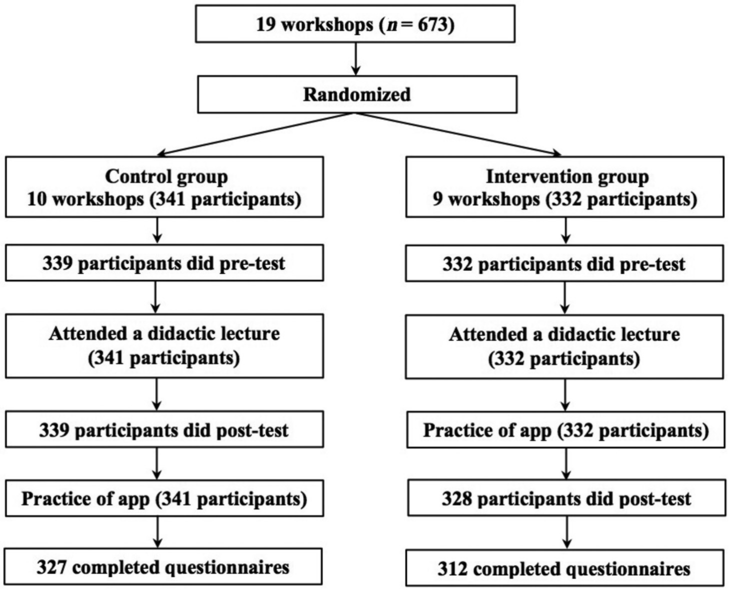

Fig 1–Flowchart of the research study.

Intervention

Intervention consisted of two consecutive sessions: lecture and practice session. The didactic lecture using slide presentations was given regarding concepts of sample size, types of data, central limit theorem, and sample size formulae for various types of study designs. Examples and parameters were drawn from published articles. In the practical session, all participants were instructed as to how to install and use the n4Sudies app to calculate sample sizes of the examples given in the lectures using their smartphones or tablets. The lecture and practical session took approximately 45 minutes each to conduct and were provided by the same instructor throughout the entire study.

Slide presentation

Slide presentation was developed based on theories related to sample size calculation, such as central limit theorem, sample calculation for estimating a given population mean/proportion, sample calculation for comparison of two means/proportions and sample size calculation for various epidemiological study designs under consultation of experts in biostatistics from two well-known universities in Thailand.

Smartphone app

Among several smartphone apps available, n4Studies was the most recently developed at the time of study. It is an app for sample size calculation on smart

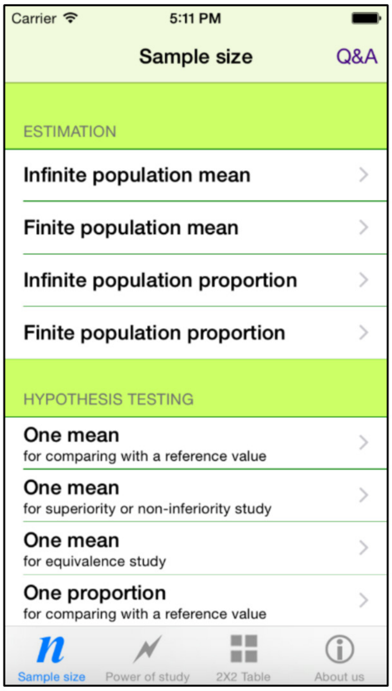

Fig 2–n4Studies app screen for iPhone system.

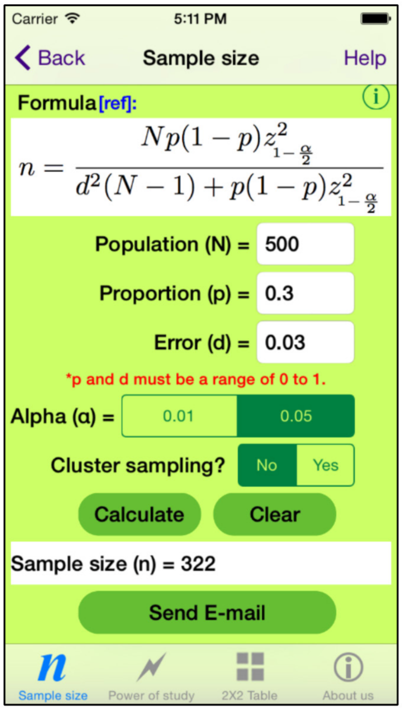

Fig 3–Screen on n4Studies app for calculation of sample size.

devices and works off-line on iPhone or Android operating systems (Ngamjarus and Chongsuvivatwong, 2014a, b). It can be downloaded free of charge from Apple app store or Google play store. Previous study found that n4Studies gives similar results to other computer softwares when using the same formula and same parameters (Ngamjarus *et al*, 2016). Users simply choose the desired sample size formula from the app screen (Fig 2) and then enter the values of parameters. Results are presented with the formula and references (Fig 3). With a touch screen and numeric keypads, parameters are readily changed and the new sample size is displayed. Results are immediately ready to be sent via e-mail on the smartphone.

Pre- and post-test

Participants were assessed using the same instrument at the pre-test (before the training workshop) and post-test (after lecture in control group and after practical session in intervention group). Control group participants were allowed to use a calculator installed on their smartphones, while those in intervention group conducted post-test assessment at the end of the practical session and were allowed to use the n4Studies app. Both pre- and post-tests needed to be completed within 10 minutes. It consisted of 10 multiple-choice questions (eight on theory, two on actual calculation) (details available on request) and were validated by three experts. Pre- and post-test assessments consisted of the same questions but given in a different order. Total score of each test (maximum of 10 points) was determined based on the number of correct answers.

Questionnaire

The questionnaire was separated into two parts: 1) demographic data and 2) attitude towards using the smartphone app. For attitude assessment, nine questions were designed using nine 5-point Likert scale items (strongly disagree, disagree, neutral, agree, or strongly agree) with Cronbach's alpha coefficient of 0.79. Participants from both groups completed the questionnaire at the finish of each workshop.

Data analysis

Pre- and post-test scores and questionnaire data were entered into a computer using EpiData (Lauritsen and Bruus, 2000), validated and exported for analysis. Descriptive statistics were used to summarize demographic data and pre- and post-test scores. Paired *t*-test was used to compare pre- and post-test scores by the same person. Independent *t*-test and 95% confidence interval (CI) were used to compare pre-test and post-test scores. Cohen's *d* value was calculated to evaluate the effect sizes. Z-test for two proportions was used to compare the proportion of correct answers in post-test assessment between the two groups. Before modelling, missing values were imputed by chained equations (Buuren *et al*, 2014). Simple and multiple linear regressions were used to investigate factors influencing post-test scores. R software with epiDisplay package (Chongsuvivatwong, 2015) was used for data management. Cohen's *d* value was calculated using effsize package (Torchiano, 2015). Missing values were imputed using mice package (Van Buuren and Groothuis-Oudshoorn, 2011). Attitude data was analyzed using likert package (Bryer and Speerschneider, 2014). Survey package (Lumley, 2014) was employed to adjust for intra-cluster correlation among participants in the same group.

Ethical considerations

The study was approved by the Ethics Committee of the Faculty of Medicine, Prince of Songkla University. All participants were informed about the rationale and objectives of the research project and those who agreed to participate were asked to sign an informed consent form. Participants' names and other personal information were kept in locked files in the principal investigator's workplace.

RESULTS

Demographic data

Nineteen workshops were conducted across four provinces of Thailand with a total of 673 participants. The mean (standard deviation) workshop size was 35 (16). Three hundred thirty-two participants were assigned to the intervention and 341 to control group. Six hundred seventy-one participants completed the pre-test (two in the control group failed to complete the test), and 339 (99%) participants in control and 332 (99%) in intervention group completed the post-test (Fig 1). Age and sex distribution were well balanced, but more participants in control group had studied mathematics, statistics, epidemiology, and research methodology. The majority of both groups had problems in both theoretical and practical aspects of sample size calculation (Table 1).

Comparison of test results

Compared to the intervention group, more participants in the control group had lower post-test scores (Fig 4). When pre- and post-test scores of the 19 workshops were compared, in all workshops, the mean scores increased from pre- to post-tests (Fig 5). However, improvements were larger in the intervention group. A comparison of the overall mean test scores between the two groups at baseline (pre-test) and after the lecture (post-test) showed a significant difference

Table 1
Demographic characteristics of participants.

Variable	Control group (n = 341)	Intervention group (n = 332)
Age group (years), n (%)		
<30	150 (48)	149 (52)
30-50	144 (46)	108 (38)
>50	17 (5)	27 (9)
Age (median, IQR)	30 (27, 37)	29 (26, 39)
Gender, n (%)		
Female	226 (70)	224 (72)
Male	98 (30)	86 (28)
Occupation, n (%)		
Student	30 (9)	33 (11)
Lecturer	17 (5)	19 (6)
Physician	54 (17)	29 (9)
Nurse	46 (14)	60 (19)
Public health officer	43 (13)	43 (14)
Medical resident/fellow	62 (19)	79 (25)
Researcher/research assistant	28 (9)	16 (5)
Other	39 (12)	32 (10)
Likes mathematics, n (%)		
No	118 (37)	117 (38)
Yes	202 (63)	190 (62)
Likes statistics, n (%)		
No	161 (50)	183 (59)
Yes	156 (49)	122 (40)
Never studied	2 (0.5)	3 (1)
Likes epidemiology, n (%)		
No	130 (40.5)	146 (50)
Yes	156 (49)	118 (39)
Never studied	35 (11)	41 (13)
Likes research methodology, n (%)		
No	127 (40)	149 (48)
Yes	179 (56)	145 (47)
Never studied	15 (5)	13 (4)
Experience in conducting research, n (%)		
No	113 (35)	122 (40)
Yes	209 (65)	184 (60)
Plans to conduct research within the next three months, n (%)		
No	109 (34)	82 (27)
Yes, writing up the research project	115 (36)	135 (44)
Yes, doing the research now	96 (30)	90 (29)
Difficulties in calculating sample size[a], n (%)		
None	19 (6)	15 (4)
Don't know which formula to select	226 (66)	217 (65)
Don't know where I can find the right formula	109 (32)	99 (30)

Table 1 (Continued).

Variable	Control group (n = 341)	Intervention group (n = 332)
Don't know the parameters in the formula	167 (49)	153 (46)
Don't know who to consult for advice or confirmation	82 (24)	86 (26)
Cannot calculate the sample size even if I know the one correct	124 (36)	116 (35)
Don't understand the formula	162 (47)	162 (49)
Software for sample size calculation is too expensive	14 (4)	17 (5)
I have the software to calculate the sample size but I don't know how to	60 (18)	51 (15)
Other	11 (3)	3 (1)
Experience using a statistical program for sample size calculation, n (%)		
No	190 (61)	158 (53)
Yes	123 (39)	142 (47)

Unless stated, numbers in the table are frequency and numbers in brackets are percentages. [a]Multiple response questions and percentages may not sum to 100%.

in post-test scores between the two groups (Cohen's d value = -0.39, $p < 0.001$), but no significant difference in pre-test scores between the two groups ($p = 0.111$) (Fig 6). The mean score in the control group increased by 1.6 points (95% CI: 1.4 - 1.8), whereas the score in the intervention group increased by 2.7 points (95% CI: 2.4 - 2.9). In the post-tests, participants in intervention group have a significantly higher proportion of correct answers to question number 6 and 7 (involving direct calculation) and to question numbers 3, 8 and 10 (theoretical) than those in control group (Fig 7).

When factors influencing post-test scores were taken into account (Table 2), participants in the intervention group have 0.9 point post-test score, significantly higher than those in the control group (adjusted coefficient = 1.0 point, 95% CI: 0.4 - 1.5). Experience in conducting one's own research was associated with significantly higher post-test scores (0.9 point, 95% CI 0.5 - 1.4) than those who did not have a plan to conduct research.

Attitude towards using the smartphone app

The score distributions of all items [nine 5-point Likert scale items (strongly disagree, disagree, neutral, agree or strongly agree)] were similar between the two groups (Fig 8). The majority of the participants in both groups perceived that the app was useful, easy for calculating a sample size and has sufficient formulae for sample size calculations.

DISCUSSION

Training on sample size calculation using a smartphone app in addition to lecture gave substantially better results than lecture alone. The smartphone app was effective in assisting participants who had a poor background in mathematics, statistics, epidemiology and research methodology. The improvement was observed in both practical calculation and in theoretical knowledge. Improvements were better among those planning to conduct their own research.

Windish *et al* (2007) studied medical

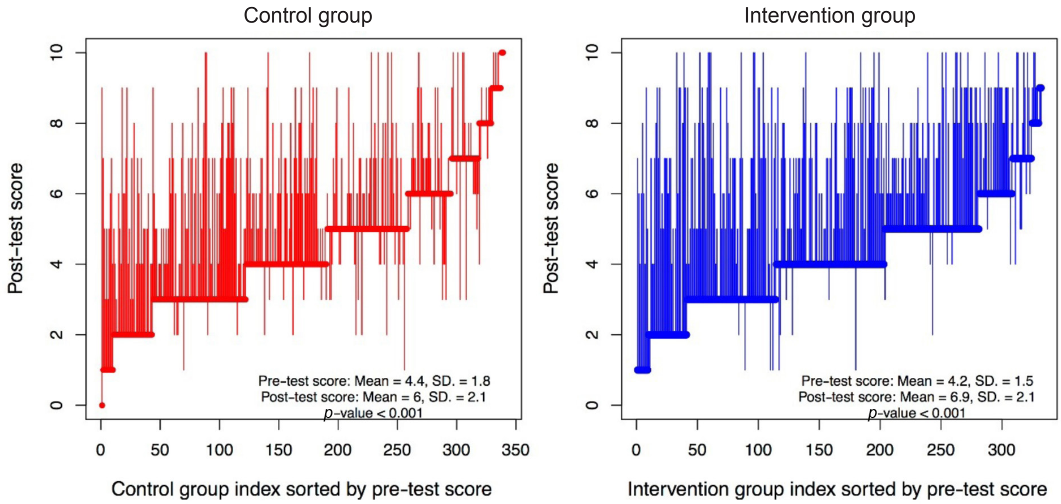

Fig 4–Comparison of post-test scores sorted by pre-test scores. Y-axis represents pre-test (large solid dots) and post-test (small dots) scores joined with vertical lines. X-axis represents index of participants sorted by pre-test scores. Lines extending upwards and downwards indicate increase and decrease in post-test scores, respectively, with length of each line representing the amount of change in score from pre- to post-test.

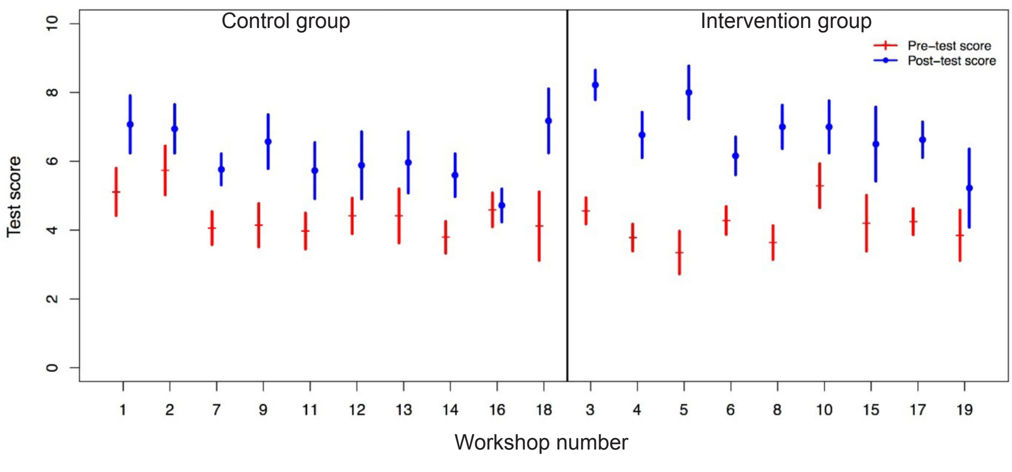

Fig 5–Comparison of mean test scores (dots) and 95 confidence interval (vertical lines) according to training workshops held.

residents' understanding of biostatistics and concluded that the majority are not competent in interpreting of results of clinical research articles. Based on a review of the literature, Garfield and Ben-Zvi (2007) concluded that there is a need to revise the traditional teaching method in statistics and that an instructional software could be a useful tool for teaching abstract ideas. Freeman *et al* (2008)

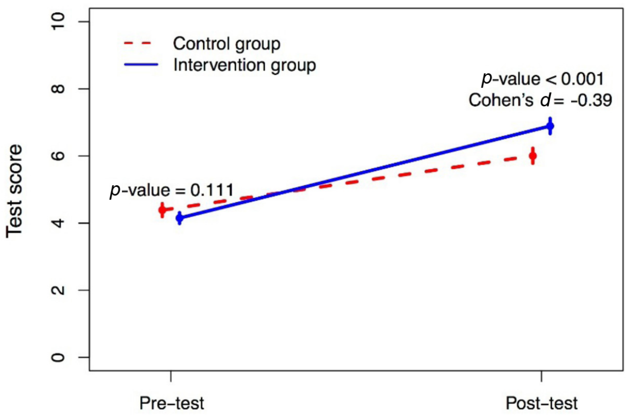

Fig 6–Comparison of overall mean test scores from control and intervention groups.

compared teaching approaches in statistics for undergraduate medical students and concluded that teaching with a variety of media, with emphasis on interpretation, can help in learning and understanding of statistics more than the traditional teaching styles. Similar to our findings, a study conducted in Germany among third-year medical students in pharmacology found a high prevalence and acceptance of mobile applications when used in conjunction with conventional teaching methods (Gutmann *et al*, 2015).

This study shows that smartphone app was not just a simple calculation tool but

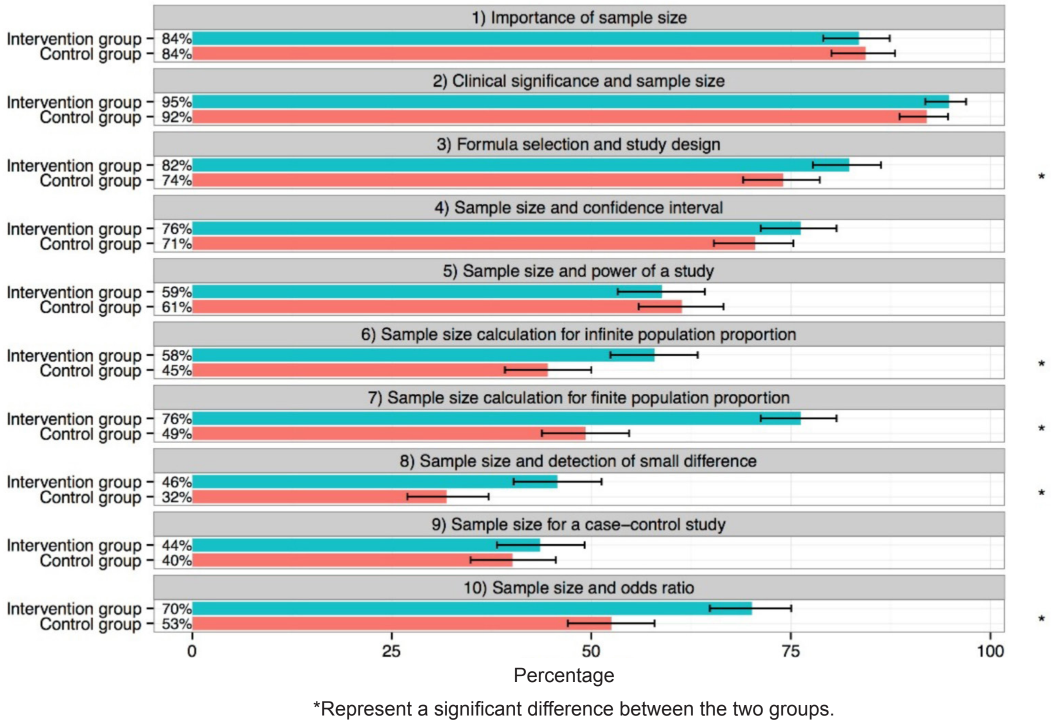

Fig 7–Percent correct answers for each post-test question.

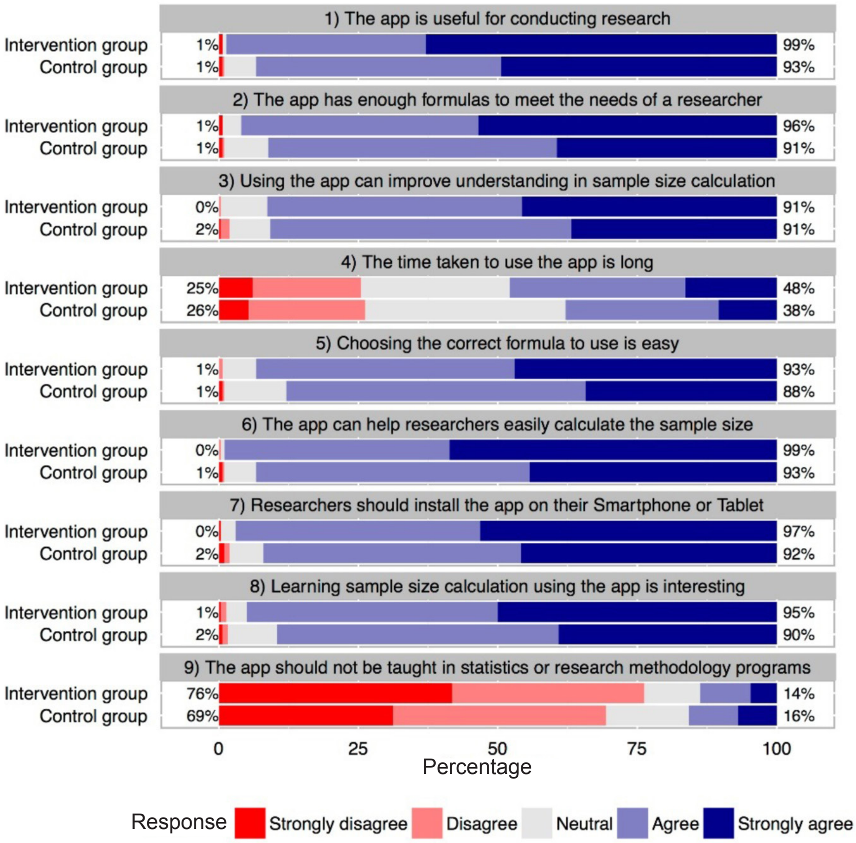

Fig 8–Comparison of participants' attitudes towards using n4Studies app. Nine questions were designed using nine 5-point Likert scale items (strongly disagree, disagree, neutral, agree, or strongly agree) with Cronbach's alpha coefficient of 0.79.

also a good medium for education in practical statistics. It is potentially useful for those who have minimal background in statistics, the majority of whom were non-researchers. Use of a smartphone app for sample size calculation could supplement or even replace teaching of theory using computer-based software. Instead of spending time memorizing or looking up a formula, use of a smartphone app will enable researchers and students to acquire quickly the correct answer, thus leaving time to focus on relationships among parameters and the results. Thus, a smartphone app can be a useful tool for teaching sample size calculations. However, didactic lectures and tutorials are still essential for students who want to learn how to calculate sample sizes for their particular research projects.

This study has a number of limitations. Firstly, the individual learning outcome was evaluated by post-test in a short time (10 minutes), and participants did not assess their knowledge for a long period. Secondly, participants in the intervention group performed post-test after learning sample size calculation by lecture and practised using the n4Studies app, thereby having more time for learn-

Table 2
Summary of regression results displaying factors influencing post-test scores.

Factor	Crude estimate (95% CI)	Adjusted estimate (95% CI)
Study group		
Control	Reference	Reference
Intervention	0.9 (0.5,1.2)	1.0 (0.4, 1.5)
Gender		
Female	Reference	Reference
Male	-0.1 (-0.4, 0.3)	-0.2 (-0.5, 0.1)
Age group (years)		
<30	Reference	Reference
30 - 50	-0.4 (-0.8, -0.1)	-0.2 (-0.7, 0.3)
>50	-0.8 (-1.4, -0.2)	-0.6 (-1.3, 0.1)
Occupation		
Student/unemployed	Reference	Reference
Lecturer	-0.8 (-1.7, 0.0)	-0.6 (-1.8, 0.6)
Physician	0.1 (-0.5, 0.8)	0.3 (-0.4, 0.9)
Nurse	-1.1 (-1.7, -0.4)	-0.6 (-1.5, 0.4)
Public health officer	-1.2 (-1.9, -0.6)	-0.9 (-1.5, -0.3)
Medical resident/fellow	-0.3 (-0.9, 0.4)	-0.2 (-1.4, 0.9)
Researcher/research assistant	-0.6 (-1.4, 0.2)	-0.2 (-0.9, 0.6)
Other	-1.2 (-1.9, -0.5)	-0.7 (-1.3, 0.0)
Likes mathematics		
No	Reference	Reference
Yes	0.3 (-0.1, 0.6)	0 (-0.4, 0.5)
Likes statistics		
No	Reference	Reference
Yes	-0.1 (-0.4, 0.3)	0.1 (-0.4, 0.7)
Never study	-1.2 (-2.2, -0.2)	-0.5 (-1.7, 0.7)
Likes epidemiology		
No	Reference	Reference
Yes	-0.2 (-0.6, 0.1)	0.1 (-0.4, 0.6)
Never studies	-0.9 (-1.4,-0.4)	-0.4 (-0.9, 0.2)
Likes research methodology		
No	Reference	Reference
Yes	-0.2 (-0.5, 0.1)	0 (-0.3, 0.4)
Never studies	-1.1 (-1.8, -0.3)	-0.3 (-1, 0.4)
Has experience in conducting a research		
No	Reference	Reference
Yes	-0.3 (-0.6, 0.0)	-0.2 (-0.6, 0.2)
Plans to conduct research within the next three months		
No	Reference	Reference
Yes, I'm writing a research proposal now	0.6 (0.2, 1.0)	0.2 (-0.1, 0.6)
Yes, I'm doing a research now	1.2 (0.8, 1.6)	0.9 (0.5, 1.4)
Has difficulties in calculating sample size		
No	Reference	Reference
Yes	0.8 (0.2, 1.5)	0.7 (-0.1, 1.4)

ing than participants in the control group who studied by lecture only before being examined by the post-test. The difference in learning time might have effect the learning outcome.

Our study demonstrates that teaching calculation of sample size with a smartphone app could significantly improve knowledge and attitude of the trainees towards this topic. We therefore suggest smartphone app should be incorporated into routine teaching in of this subject.

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