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TITLE Characterising the use, users and effects of a health app supporting lifestyle changes in pregnant women

YEAR 2022

DOI <https://doi.org/10.1017/S0007114522003439>

VERSION Author's accepted manuscript

CITATION Koivuniemi, E., Raats, M., Ollila, H., Löyttyniemi, E., & Laitinen, K. (2022). Characterising the use, users and effects of a health app supporting lifestyle changes in pregnant women. *British Journal of Nutrition*, 1-13. doi:10.1017/S0007114522003439

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Characterising the use, users and effects of a health app supporting lifestyle changes in pregnant women

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Short title: Health app in pregnancy

Key words: gestation, smartphone, gestational weight, diet quality, physical activity



This peer-reviewed article has been accepted for publication but not yet copyedited or typeset, and so may be subject to change during the production process. The article is considered published and may be cited using its DOI

10.1017/S0007114522003439

The British Journal of Nutrition is published by Cambridge University Press on behalf of The Nutrition Society

ABSTRACT

The study objective was to 1) compare, through a randomised pilot intervention study, the effects of a standard health app and an enhanced health app, with evidence-based information regarding healthy lifestyle, on gestational weight gain, diet quality and physical activity in pregnant women. The sub-objectives were to 2) characterise app use and users among pregnant women and to 3) compare, in the overall sample regardless of the intervention, whether the frequency of the health app use has an effect on the change in gestational weight, diet quality and physical activity. Women recruited through social media announcements (n=1038) were asked to record their lifestyle habits in the app from early pregnancy to delivery. Self-reported weight, diet quality and physical activity were assessed in early and late pregnancy with validated online questionnaires. No benefits of the enhanced app use were shown on the lifestyle habits. Nevertheless, frequent app users (use \geq 4.7 weeks) in the enhanced app group had a higher physical activity level in late pregnancy compared to those in the standard app group. Overall, extensive variation was found in the number of recordings (median 59, interquartile range 19–294) and duration of app use (median 4.7, interquartile range 1.1–15.6 weeks). Frequent app users had higher education level, underweight/normal weight, better diet quality and were non-smokers, married and primipara more likely than occasional app users or non-users. Physical activity levels among app users decreased less compared to non-users over the pregnancy course, indicating that app use could motivate to maintain physical activity during pregnancy.

Registration information: [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT05094479), NCT05094479

INTRODUCTION

Lifestyle factors such as obesity, an unhealthy diet and low physical activity level have been related to increased risks for significant pregnancy complications, such as gestational diabetes^(1,2). Healthy lifestyle habits may thus be considered as highly desirable, and pregnancy can serve as a window of opportunity for promoting lifestyle changes to support the health of the baby⁽³⁾. However, lifestyle changes are difficult to implement as is evident from a number of intervention studies in which the compliance and thus the results of the intervention have been, at best, modest^(4,5). Common barriers to adopting a healthy lifestyle during pregnancy include tiredness, lack of time, support and knowledge regarding health^(6,7) as well as the lack of resources to effectively support lifestyle changes with respect to health care⁽⁸⁾.

In recent years, smartphone use has become very widespread and in Finland almost every person in the 16- to 44-year-old age range (i.e. 97 to 100%) possesses a smartphone⁽⁹⁾. In this context, health apps may offer an under-utilised solution for supporting lifestyle changes and allowing self-monitoring during pregnancy⁽¹⁰⁾. Self-monitoring is a behavioral change technique, based on a social cognitive theory of self-regulation⁽¹¹⁾, widely incorporated into health apps^(12–14). Previous studies, although with relatively small sample sizes, have found that health technology may offer a useful approach for self-monitoring and can provide encouragement in adopting a health-promoting lifestyle during pregnancy. Some examples of these changes are prevention of excess gestational weight gain^(15–17), adopting healthy dietary habits^(18–20) and maintaining physical activity^(17,19). Although there are thousands of health apps available globally, rather few have been evaluated in terms of their scientific validity⁽²¹⁾.

Health apps have become an important source of information for pregnant women^(22,23) and in general pregnant women are interested in gaining information, especially on healthy eating, weight management and exercise⁽²⁴⁾. However, the available information is often not evidence-based⁽²¹⁾. There is some evidence suggesting that even simple advice from health care professionals may be as effective in the promotion of healthy dietary habits and physical activity⁽²⁵⁾. Thus, health information backed by health professionals and delivered via the app could potentially improve the health-promoting effects of self-monitoring, but at present there is little published material to support this speculation. Furthermore, despite the high number of available health apps, there is limited understanding of the extent to which these are used and what characterises app users as opposed to non- or limited users. As it seems likely that

adherence is a crucial factor for health apps supporting the health-promoting habits^(26,27), we deemed it important to investigate the frequency and duration of health app use and the factors impacting on their use.

The aims of the current study were 1) to determine whether the addition of evidence-based information on health-promoting lifestyle delivered via the health app would exert an effect on the change in gestational weight, diet quality and physical activity during pregnancy (pilot intervention trial), 2) to characterise the health app use (the number, type, frequency and duration of recordings in the app) and users (demographic factors) among pregnant women and 3) to investigate whether the frequency of the health app use has an effect on the change in gestational weight, diet quality and physical activity.

METHODS

Study participants and setting

Pregnant women were recruited in a follow-up study with a 2-arm equal allocation parallel randomised controlled pilot trial of a digital intervention in Finland between June and October 2017, with data collection completed on August 2018. The data were also used to characterise app use and users among pregnant women and to study the effects of app using frequency on the change in lifestyle habits. As pregnant women using mobile devices were the target population, social media was used in the recruitment drive. Women less than 28 weeks pregnant and fluent in Finnish were invited to the study. Women interested in participating in this project contacted the researcher through an attached electronic form in the social media announcements. An electronic questionnaire was sent to the eligible women within a week (early pregnancy questionnaire, gestational weeks 4-27 (median 14.4, interquartile range 9.6–20.1 weeks)). In late pregnancy (gestational weeks 33-40 (median 36.0, interquartile range 35.5–36.6 weeks)), the women completed a second questionnaire (late pregnancy questionnaire). The study flow is depicted in detail in Figure 1.

After completing the early pregnancy questionnaire, participants were sent a web link to download one of two apps that delivered the intervention. At this point, the women were randomised into two groups: until delivery, women used either a standard version of the health app, later referred as the ‘standard app group’, or an enhanced version of the health app, later referred to as the ‘enhanced app group’. Randomisation was undertaken by an online random

number generator, using a block size of 6, arranged in their order of contacting the researchers. Researchers sent non-personalised information on healthy lifestyle during pregnancy through the app only to the participants in the enhanced app group. Both apps served as a tool for self-monitoring, i.e. recording lifestyle habits, including weight, diet, and physical activity during pregnancy.

To answer to the first aim, questionnaire data on lifestyle factors (gestational weight gain, diet quality and physical activity) in early and late pregnancy were collected to study the intervention effect in a pilot trial. For the second aim, data on the number, type, frequency and duration of recordings during the study period were collected with the app and women's demographic factors with a questionnaire in early pregnancy. For the third aim, data on the app use frequency during the study period as well as questionnaire data on lifestyle factors in early and late pregnancy were used for the analyses. For these analyses, women were categorised as frequent users, occasional users and app non-users. Data collection and data used for the analyses are presented in Figure 2.

The study received an ethical approval from the Ethics Committee of University of Turku, Finland (statement 62/2016) and the study was conducted in accordance with the Declaration of Helsinki and its later amendments. Informed consent to participate in the study was gathered electronically from all women. The study was registered in ClinicalTrials.gov (registration number NCT05094479).

Questionnaires

Structured questionnaires in early and late pregnancy inquired about background factors, such as previous health app use, socioeconomic status and overall health (only in early pregnancy, response options in Table 1), as well as weight, diet quality and physical activity. User experiences regarding the app were gathered in late pregnancy with a questionnaire including 16 statements with response options listed on a Likert scale (strongly agree, agree, not sure, disagree, or strongly disagree; Supplementary Table 1).

Weight

Participants reported their pre-pregnancy weight, current weight and height in the early pregnancy questionnaire, and current weight was reported again in late pregnancy. Pre-pregnancy body mass index (BMI) was calculated as pre-pregnancy weight divided by height squared. Gestational weight gain was calculated as the difference in self-reported weight

between late pregnancy and pre-pregnancy, and weekly gestational weight gain by dividing the gestational weight gain by the weeks of gestation.

Diet quality

Diet quality in accordance with the national nutrition recommendations was assessed by a validated Index of Diet Quality (IDQ) consisting of 18 questions about the consumption of food items such as whole-grain, spreads, dairy, vegetables, fruits and berries and sugar-rich foods⁽²⁸⁾. The IDQ score ranges from 0 to 15 points⁽²⁸⁾. If there were three or more missing answers, the IDQ score was not calculated.

Adherence to dietary recommendations was evaluated by comparing diet quality components, chosen from the IDQ questions, with Nordic and Finnish dietary recommendations^(29,30). The diet quality components were: eating vegetables, fruit and berries at least 5 portions a day (yes/no), eating fruit and/or berries daily (yes/no) and regular eating frequency (2 meals skipped per week, yes/no).

Physical activity

Physical activity was measured using a validated metabolic equivalent (MET) index that consists of three multiple-choice questions concerning the intensity, frequency and duration of physical activity⁽³¹⁾. The total MET score ranges from 0 to 105 MET h/wk⁽³¹⁾. The MET scores were categorised as follows: scores <5 MET h/wk indicate light, scores ≥ 5 but ≤ 30 MET h/wk moderate and scores >30 MET h/wk vigorous physical activity. Level 5 MET h/wk corresponds to one hour of moderate-intensity physical activity per week while level 30 MET h/wk corresponds to one hour of moderate-intensity physical activity per day⁽³¹⁾. The total MET score was calculated if the participant had answered all three questions.

App

The health app (Dottli, Dottli Oy, Espoo, Finland), originally developed for supporting the self-care of diabetes, is available for use with iOS and Android operating systems and via web browsers. Minor modifications were made to the app for research purposes, i.e. features allowing the participant to record simple dietary measures, including their fruit and vegetable intakes, were added and participants were prevented from hiding their recordings from the

researchers. The research version of the app was piloted with 10 women of childbearing age after which the study was started without further modifications to the app.

Participants were instructed to record their lifestyle information in the app regularly from early pregnancy until delivery. There were several types of recording types available e.g. weight (in kilograms), number of fruit and vegetables eaten in a day, type of meals eaten in a day (breakfast, lunch, snack, dinner, evening snack), mood (excellent, good, ok, bad, horrible) as well as the time, type and intensity of physical activity. If the participant had a compatible physical activity tracker, they were able to link it with the app to transfer the physical activity data to the app. Participants were able to monitor the possible changes in their lifestyle habits by viewing graphs of their recordings. The app also gave automated feedback on blood glucose levels to women with gestational diabetes who recorded their blood glucose levels in the app. Both the standard app and enhanced app groups received weekly reminders via the app that encouraged them to make recordings regularly. The reminders had a weekly theme: participants were specially recommended to record their weight, intake of fruit and vegetables, number of daily meals, and the amount and/or type of physical activity in a given week. Participants could use all recording types as often as they wished irrespective of the themes of the reminders. All participants received an instruction sheet detailing how to log in and use the app and its features. App data including the time, date and type of recordings was collated from the app in Microsoft Excel (version 2016) format.

Pilot intervention

The pilot intervention involved two groups. Women in the enhanced app group received additional, non-personalised information on health-promoting lifestyle during pregnancy via the app. All the information was based on expert opinion based on national recommendations about diet, physical activity and weight gain during pregnancy^(29,30,32,33). The information i.e. tips on health-promoting eating habits, exercise, appropriate gestational weight gain and risks of gestational diabetes, were sent weekly. The tips were constructed to motivate the participants to engage in a health-promoting lifestyle and to inform about the potential risks related to an unhealthy lifestyle, e.g. risk of gestational diabetes. The standard app group did not receive any additional information on health-promoting lifestyle via the app.

Outcome variables

In the pilot intervention (only app users included in the analyses), outcome variables were changes in gestational weight gain and diet quality scores between early and late pregnancy. Further outcomes were changes in physical activity scores between early and late pregnancy, as well as the proportion of women with diet quality components in accordance with dietary recommendations in early and late pregnancy.

To characterise the participants and app users, background factors such as previous health app use, socioeconomic status and overall health were used. App use was characterised by using data recorded in the health apps and app user experiences.

Outcome variables for investigating the effects of app use frequency (all women included in the analyses independent of the app version used) were changes in gestational weight, diet quality, diet quality components and physical activity between early and late pregnancy.

Statistical analysis

For exploratory purposes, a large sample size ($n=1000$) in comparison to previous studies investigating health apps during pregnancy (n typically 10 to 218^(15–18,20,34)) was sought. The power calculations were not performed for the intervention as it is considered a pilot study, the results of which can be used to calculate the power for a larger study. No imputations were conducted as a result of missing data. The normality of the data was observed from histograms with Kolmogorov–Smirnov test. Normally distributed variables are presented as means and standard deviations and non-normally distributed data as medians and interquartile ranges. Categorical data are summarised as frequencies and percentages. For continuous data, T-tests were used for normally distributed variables and Mann-Whitney U tests for non-normally distributed variables to compare the differences in lifestyle factors between enhanced and standard app groups (analyses included app users). When investigating the differences in IDQ scores between the enhanced and standard app groups (analyses among all app users and frequent app users only), an additional linear mixed model analysis was conducted to control for potential confounding factors (mother's age, parity, marital status, educational level and pre-pregnancy BMI). One-way ANOVA was used for normally distributed variables and Kruskal-Wallis test for non-normally distributed variables when comparing the differences in lifestyle factors between frequent, occasional and app non-users (analyses included all women independent of the app version used). Comparisons for categorical data were made with

Fisher's exact test or Chi-square test. A logistic mixed model for repeated measures was used to analyse the change in categorised data between early and late pregnancy. As there were only limited data on blood glucose levels ($n=51$ recorded blood glucose data) especially in late pregnancy, no further analyses regarding blood glucose levels were conducted. Regarding the data on app user experiences, 'strongly agree' and 'agree' as well as 'strongly disagree' and 'disagree' answers were combined and women answering 'not sure' were excluded from the analyses. The level of significance was set to p -value <0.05 . Statistical analyses were carried out using SAS version 9.4 (SAS Institute, Cary, NC, USA) and IBM SPSS Statistics for Windows, version 27 (IBM Corp, Armonk, NY).

RESULTS

Demographic characteristics

In all, 1517 women were assessed for eligibility and 1038 women were included in the analyses (Figure 1). Demographic characteristics of the participants are presented in Table 1. A total of 514 of the participants were allocated to the enhanced and 524 to the standard app group; the characteristics of the two groups were similar at baseline, e.g. in early pregnancy (Table 1). There was a total dropout rate of 62% (647 of 1038) between early and late pregnancy, with an equal distribution in the standard app and enhanced app groups. The dropouts were more likely to be multiparous and smokers before pregnancy as well as have overweight or obesity, lower education, lower gestational weeks and lower diet quality scores in early pregnancy compared to the women continuing the study (Supplemental table 1).

Thirty-eight percent of the participants (398 of 1038) reported some app use to record their lifestyle habits prior to entering the study. Most of them had recorded their weight (79%, 313 of 398) or physical activity (76%, 302 of 398), followed by diet (53%, 209 of 398), mood (16%, 62 of 398) and sleep (12%, 46 of 398). Of these women, 60% (237 of 398) had used these apps daily or almost daily, and 70% (278 of 397) used the apps for at least a two months' period.

Pilot intervention effects on the lifestyle habits

When investigating the intervention effect on the lifestyle habits, we found no significant differences in gestational weight gain or in the changes in IDQ scores or MET scores (Table

2). The women in the enhanced app group had higher IDQ scores in early pregnancy compared to women in the standard app group ($p=0.02$), but the difference levelled off by the late pregnancy. Adjustments taking into account the mother's age, parity, marital status, educational level and pre-pregnancy BMI did not change the results regarding IDQ scores in early pregnancy (adjusted $p=0.023$), late pregnancy (adjusted $p=0.50$) or the change in IDQ scores over the study period (adjusted $p=0.25$; linear mixed model). Furthermore, there were no differences between the intervention groups in the diet quality components in early and late pregnancy (Table 2). The mixed effects logistic regression model showed that time \times group interaction for regular eating frequency was statistically significant ($p=0.041$): in the enhanced app group, the proportion of women with regular eating frequency (i.e. 2 or less meals skipped per week) was lower in late pregnancy as compared to early pregnancy (OR 0.47, 95% CI 0.22–0.98, $p=0.045$), whereas in the standard app group, there was no difference between early and late pregnancy in the proportion of women with a regular eating frequency (OR 1.44, 95% CI 0.69–3.01, $p=0.33$). No other differences were detected in the changes in the diet quality components over the course of the pregnancy (data not shown). No differences between the groups were detected in weight or MET scores in early or late pregnancy.

The effect of the intervention on the lifestyle habits was also investigated exclusively within frequent app users, but no differences were found between the standard app and enhanced app groups on gestational weight gain, changes in IDQ or MET scores (Supplemental table 2) or changes in diet quality components (data not shown). Interestingly, frequent app users in the enhanced app group had higher MET scores in late pregnancy compared to those in the standard app group ($p=0.015$). Frequent app users in the enhanced app group also had higher IDQ scores in early pregnancy compared to those in the standard app group ($p=0.04$), but this difference was no longer evident in late pregnancy. After adjusting for mother's age, parity, marital status, educational level and pre-pregnancy BMI, the difference in the IDQ scores was no longer present (adjusted $p=0.086$, linear mixed model); other results regarding IDQ data did not change.

Characterisation of app use

The majority of the participants, i.e. 76% created an account in the app and 37% made at least one recording in the app ('app users'; i.e. 63% were 'app non-users'). During the study period, the women made a median of 59 recordings, ranging from 2 to 4651. The median duration of total app use was 4.7 weeks, ranging from 0.1 to 35.1 weeks (Figure 3). The most frequent type of recording was the number of meals eaten during the day, accounting for 23% of all the

recordings, followed by water (16%), fruit (10%) and vegetable consumptions (10%). App use is reported in detail in Table 3. Based on number of recordings, app users were categorised as ‘frequent app users’ (recorded for at least 4.7 weeks) and ‘occasional app users’ (recorded at least once, but for less than 4.7 weeks) for further analyses.

When assessing the frequent app user’s experiences of using the app, it was found that the proportion of frequent app users answering that they had tried to improve their eating habits through the use of the app, was significantly higher in the enhanced compared to the standard app group (49% vs. 29%, respectively, $p=0.031$). No other differences between the groups were detected. Further details are shown in Supplemental table 3. When the frequent app users’ experiences were compared with those of occasional app users and app non-users, it was observed that frequent app users reported less difficulties in using the app as compared to the other groups. No differences were found between the groups with regard to experiencing technical problems with the app. Overall, frequent app users expressed a more positive opinion of the app and its use and were more likely to report trying to improve their lifestyle habits via the app than the women in the other groups. User experiences among frequent app users, occasional app users and app non-users are presented in Supplemental table 4.

Characterisation of app users

The frequency of app use was significantly associated with several background factors (Table 4). The comparisons indicated that frequent app users were more likely to be underweight or normal weight ($p=0.017$) and non-smokers ($p=0.015$) before pregnancy compared to app non-users. Moreover, being married ($p=0.002$), primiparous ($p=0.001$), and having a university education ($p=0.005$) were more likely in frequent users than in non-users. Occasional app users were more likely to have a university education than the non-users ($p=0.001$). Furthermore, frequent app users had significantly higher IDQ scores than non-users in early pregnancy ($p=0.002$, Table 5). The proportion of women eating fruits and/or berries daily was also higher in frequent app users compared to app non-users in early pregnancy ($p=0.006$) and to occasional app users in late pregnancy ($p=0.004$, Table 5).

Effects of the app use frequency on the lifestyle habits

No significant differences were detected between frequent, occasional and app non-users with respect to the changes in gestational weight, IDQ scores and diet quality components, or MET scores between early and late pregnancy (Table 5). In the mixed effects logistic regression model, it was found that time was statistically significantly associated with the categorised

MET as the proportion of women with high or moderate activity level was lower in late pregnancy as compared to early pregnancy (OR 0.54, 95% CI 0.43–0.67, $p < 0.0001$). The time \times group interaction was also statistically significant (p -value=0.036); the proportion of women with high and moderate activity decreased more in app non-users than in frequent app users (OR 0.61, 95% CI 0.40–0.94, $p=0.025$) and occasional app users (OR 0.55, 95% CI 0.32–0.97, $p=0.04$).

DISCUSSION

We found that the pilot intervention did not have any impact on altering lifestyle habits. Nonetheless, it is important to note that frequent app users in the enhanced app group had a higher level of physical activity (MET scores) in late pregnancy compared to those in the standard app group suggesting that a combination of frequent app use with additional evidence-based health information delivered via the app might be beneficial in maintaining the physical activity level over the course of the pregnancy. We also observed an extensive range in the use of a health app and several demographic factors that characterise frequent app use. Furthermore, the results indicate that physical activity levels amongst app users decreased less than in app non-users over the course of pregnancy. However, app use frequency did not have an effect on the change in gestational weight or diet quality.

Pilot intervention effects on the lifestyle habits

As far as we are aware, this is the first study to investigate whether evidence-based health information delivered solely via a health app could motivate women to undertake healthy lifestyle changes during pregnancy. In several intervention studies, health information has been delivered face-to-face e.g. during health clinic appointments or in combination with a smartphone app or other online method^(16,18,19,35). It has been suggested that an online intervention could be as efficacious but more accessible and cost-effective than the more traditional methods^(15,36), and thus we were interested to investigate the effects of an online-only intervention. However, this pilot intervention found no effects on the lifestyle habits during pregnancy. Despite a higher rate of dropouts than expected, we would not expect to see any effects on the lifestyle habits in a larger study population, because differences between groups were small and therefore not clinically meaningful.

There were many potential reasons why the intervention did not work as expected. One possible reason could be that the intervention messages sent to the participants should have been more frequent than once a week. Some previous intervention studies have even had daily contact with the participants via text-messages, e-mails or phone calls ^(16,37,38), but there are also online intervention studies reporting only monthly contacts with the participants ⁽³⁹⁾. In fact, it has been stated that information on physical activity should not be delivered daily to pregnant women as this type of frequency may even inhibit the women from becoming physically active ⁽⁴⁰⁾. Although these are not strictly app-based studies, the results nevertheless indicate that the rate of intervention messages in this study seemed to be acceptable. In addition, it has been observed that if the intervention is delivered without face-to-face contact to the participants, the dropout rates might be fairly high ^(39,41–43). In our study, the intervention messages were not personalised, which might also explain the modest changes in the lifestyle habits. It has been suggested that highly personalised interventions would be more effective if they could be tailored to each participant's individual needs ⁽⁴⁴⁾. It is noteworthy that lifestyle changes during pregnancy are known to be difficult to implement even in those intervention studies delivering personalised face-to-face counselling ^(45,46). Interestingly, the frequent app users in the enhanced app group did report that they had tried to improve their eating habits as a whole via the stimulus provided by the app (Supplemental table 3), although this was not translated into actual changes in their dietary habits.

This pilot intervention suggests that should a larger intervention trial be planned, it could benefit from more personalised or frequent messaging about lifestyle habits in an attempt to engage the women more in the intervention and to try to avoid the high dropout rate encountered here; e.g. machine learning could be of help in creating personalised feedback and better motivation for the participants. The sample size of the larger intervention trial could be calculated with gestational weight gain as the primary outcome. In this study, the mean (SD) gestational weight gain in the standard app group was 9.6 (5.3) kg. To detect a 10% decrease in the gestational weight gain in the enhanced app group, the required sample size should be 641 participants per group (statistical power of 90% and a significance level of 0.05). When allowing for a 40% drop-off rate, this means that the targeted sample size should be about 1070 participants per group.

Characterisation of app use and users

Whilst it was expected that pregnancy might be a motivating time for self-monitoring of lifestyle habits, the overall level of the app use was low as only a third of the original participants made any recordings in the app and the median time of app use was less than five weeks. This mirrors previous studies showing low overall health app usage^(19,35). One possible explanation could be that women interested in participating in the study might have concurrently been using some other health app and not have wanted to use both or change it to the app supplied in this study as previous research has revealed that on average, health app users have three health apps on their smartphones, of which they only use two⁽⁴⁷⁾. Some participants in this study also reported encountering technical problems with the app, thus possibly deterring its use, although many others felt comfortable with the technical properties of the app. It has been recognised that the use of a health app is also largely effected by its features and its ability to engage its users⁽²⁷⁾, but there is no way of knowing which features are the problem; it does seem to be a matter of individual preference. The information provided here may enable the development of apps that are more user-friendly and enjoyable to use and thus potentially more effective.

It is noteworthy that women who were highly educated, underweight/normal weight and non-smokers were more likely to use the health app compared to those with a lower education and less healthy lifestyle habits. In fact, it would be truly advantageous to engage particularly those women with less education and less healthy habits who might potentially have less knowledge of what represents a healthy lifestyle⁽⁴⁸⁾ and who might be more in need of lifestyle changes; in these women, self-monitoring with this kind of health app would be especially beneficial. Previous studies investigating the association between weight and health app use in a non-pregnant population have been largely inconclusive. Some studies found that a lower BMI value was associated with more frequent health app use⁽⁴⁹⁾, but also opposite results have been reported⁽⁵⁰⁾. Furthermore, other investigators have not found any association between weight and health app use⁽⁵¹⁾. Consistent with the findings reported here, higher educational level^(47,51,52) and being married⁽⁵³⁾ have also been linked to health app use in previous studies in a non-pregnant population. Moreover, in this study, the primiparous women were more likely to use the app which might be explained by the enthusiasm of first-time-mothers and their better time resources compared to multiparous women. However, there is very little previous

evidence describing the characteristics of the typical pregnant app user; this is a topic that demands further investigation.

Effects of the app use frequency on the lifestyle habits

Some benefits of the use of the app were found: the proportion of women with high or moderate activity decreased less compared to app non-users during pregnancy. This suggests that although the amount and intensity of physical activity tend to decline throughout pregnancy⁽⁵⁴⁾, self-monitoring of physical activity with a health app could motivate pregnant women to continue to exercise into late pregnancy. The result is of relevance as maintaining physical activity during pregnancy has been linked with lower risk of pregnancy complications compared to physical inactivity⁽⁵⁵⁾. The app use frequency did not have any effect on the diet quality, even in those individuals who were monitoring their diet intensely: diet-related recording types, such as meals and consumption of vegetables and fruits, were the most frequently used recording types. App use might still have some effect on the diet quality components as frequent app users were more likely to be eating fruits and/or berries on a daily basis than occasional app users or app non-users in early pregnancy and this difference became emphasised in late pregnancy. However, the group difference in the change over the course of the pregnancy was not statistically significant. No effect on the gestational weight gain was also detected; this might be partly explained by the fact the women did not record their weight in the app extensively i.e. the weight recordings constituted only 2% of all of the recordings. In Finland, gestational weight gain is routinely followed in maternity clinics, and it is possible that most of the women did not regularly follow their weight themselves.

Strengths and limitations

This study has several strengths including a large sample size and a randomised controlled study design. Most studies using health apps have been conducted with relatively small sample sizes, thus limiting the conclusions that may be drawn from the results. Additionally, the sample of this study was found to be relatively representative of Finnish pregnant women when compared to Finnish perinatal statistics⁽⁵⁶⁾, with regards to age (29.4 vs 31.2 years, respectively), pre-pregnancy BMI (24.8 vs 25.3 kg/m², respectively), being married (50.4 vs. 53.5%, respectively) and locality, although the proportion of primiparous women was slightly higher in this sample (54.3 vs 42.3%, respectively). It is also considered as a strength that the

intervention was based on factual information on health-promoting lifestyle derived from national recommendations on diet, physical activity a gestational weight gain, and that validated indices including IDQ and MET were used to assess the lifestyle habits of the women. Furthermore, social media has been considered to be an effective recruitment channel ⁽⁵⁷⁾, especially for recruiting women and hard-to-reach populations ⁽⁵⁸⁾.

Some limitations should also be acknowledged, the major being the study's high dropout rate. However, it should be noted that a high dropout is a typical feature of online studies ^(59,60). The dropout rate was equal between the intervention groups, suggesting that the intervention was not influenced by the dropout. Nevertheless, the dropouts had lower diet quality scores in early pregnancy compared to the women continuing the study, which may partly explain why only modest changes in the diet quality were discovered, i.e. the better diet quality of those remaining in the study may have been difficult to improve. No differences were seen in the physical activity levels between the dropouts and participants who continued in the study and indeed, the app use seemed to exert some benefits on maintaining physical activity during pregnancy. Further, the dropouts were more likely to be multiparous and smokers before pregnancy and have overweight or obesity, lower education and lower gestational weeks compared to the women continuing the study, which may also result in underestimation of the intervention and app use effects. To increase the compliance, more frequent personal contact to the participants during the study period might be beneficial. Additionally, one solution for increasing the feasibility of the app could be to develop the app further with adding features that can be personalised for their own purposes, e.g. personalised appearance of the app, adding and hiding features based on personal preference. Another source of uncertainty may arise from the self-reported data as self-reporting may result in misreporting of data; for example, due to a social desirability bias ^(61,62). Furthermore, 67% of the study participants had a university degree while only 33% of Finnish adults are highly educated ⁽⁶³⁾, which might make these findings less generalisable to women with a lower socioeconomic status.

CONCLUSIONS

In conclusion, no putative benefits of providing additional evidence-based health information to supplement app use on the lifestyle habits of these pregnant women were detected, except that frequent app use combined with additional health information delivered via the app might be beneficial in maintaining the physical activity level during pregnancy. It is of note that a wide variation in both the number of recordings and duration of the health app use was observed. Frequent app users were characterised by several demographic factors including high education level, underweight or normal weight, non-smoking status, being married and primipara, as well as having higher diet quality scores and eating fruit and/or berries on a daily basis. The results also indicate that frequent health app use alone might motivate pregnant women to maintain their physical activity level throughout their pregnancy. It would be important to determine an efficient means to motivate especially those pregnant women with lower education and less healthy lifestyle habits to use the health app more regularly. Further studies with a larger sample size will be needed to confirm whether the enhanced app, i.e. the health app in combination with evidence-based information on health-promoting lifestyle, would be helpful to pregnant women.

Acknowledgements

We want to thank all the participants for making this study possible. We also thank Ewen MacDonald for the English language revision.

Financial Support

This work was supported by Business Finland (3486/31/2015). EK received personal funding from the Diabetes Research Foundation (grant number 210007), the Finnish Cultural Foundation (Varsinais-Suomi Regional Fund, grant number 85211826), the Jalmari and Rauha Ahokas Foundation (no grant number), the Juho Vainio Foundation (grant number 202100303) and the Turku University Foundation (grant number 080979). The funding sources had no role in the design, execution, analyses, interpretation of the data, or decision to submit results.

Conflicts of interest statement

The authors declare no conflicts of interest.

Author contributions

KL formulated the research question. EK and KL designed the study. EK collected the data. HO, EL and EK conducted the data analysis. EK, KL and MR interpreted the results. EK wrote the first manuscript draft. KL and MR contributed to the writing of the manuscript. KL has the primary responsibility for the final content. All authors have reviewed and revised the final manuscript.

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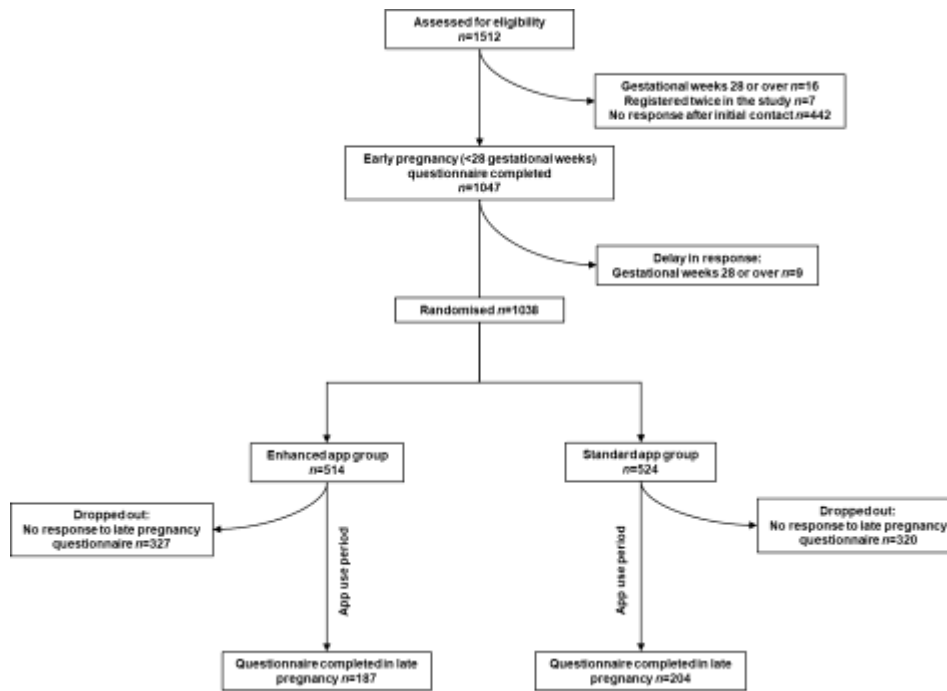


Figure 1. Flow chart of the pilot intervention trial. The data were also used to characterise the users and use of the health app by pregnant women and to study the effects of app use frequency on changes in gestational weight, diet quality and physical activity. For the latter, women were classified based on their app use: frequent users (≥ 4.7 weeks, $n=193$), occasional users (< 4.7 weeks, $n=193$) and app non-users ($n=652$).

STUDY STAGE	DATA COLLECTION		DATA ANALYSIS				
	Questionnaires	App recordings	Characterisation of app use		Characterisation of app users	Impact of app use frequency on lifestyle factors	Impact of intervention on lifestyle factors
Early pregnancy (mid gestational weeks 14.4)	Demographic information				•		
	Weight					•	•
	Diet quality					•	•
	Physical activity					•	•
Intervention period (app use)		Descriptive data on the app use	Lifestyle recording data	•	•	•	
Late pregnancy (mid gestational weeks 36.0)	App user experiences		•				
	Weight					•	•
	Diet quality					•	•
	Physical activity					•	•

Figure 2. Data collected in each study stage and use of the data in the analyses. Dots indicate the data used in each analysis.

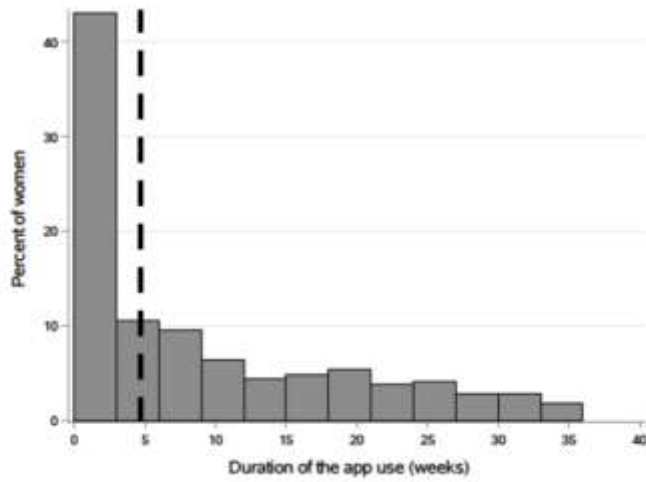


Figure 3. Duration of the app use among the participants. Dashed line denotes the median duration of the app use.

Table 1. Demographic characteristics of all participants and according to their allocation into standard app and enhanced app groups.

	Total n	All (n=1038) ^a		Standard app group (n=524) ^a		Enhanced app group (n=514) ^a		P-value
		n,	%,	n,	%,	n,	%,	
		mean or median	SD or IQR	mean or median	SD or IQR	mean or median	SD or IQR	
Age (years)	1033/522/511	29.4	4.0	29.5	3.9	29.2	4.1	0.15 ^b
Gestational weeks at early pregnancy	1038/524/514	14.4	9.6 – 20.1	14.4	9.7 – 20.1	14.4	9.6 – 20.1	0.94 ^c
Gestational weeks at late pregnancy	388/202/186	36.0	35.5 – 36.6	36.0	35.6 – 36.7	35.9	35.4 – 36.4	0.29 ^c
Pre-pregnancy BMI (kg/m²)	1035/524/511	24.8	4.9	24.8	4.8	24.8	4.9	0.90 ^b
Underweight		22	2.1	12	2.3	10	2.0	0.96 ^d
Normal weight		634	61.3	322	61.5	312	61.1	
Overweight		237	22.9	117	22.3	120	23.5	
Obese		142	13.7	73	13.9	69	13.5	
Gestational weight gain (kg)	381/198/183	9.0	6.0 – 12.0	9.0	6.0 – 12.0	9.0	6.0 – 11.0	0.39 ^c
Inadequate		64	16.8	33	16.7	31	16.9	0.52 ^d
Ideal		115	30.2	55	27.8	60	32.8	
Excessive		202	53.0	110	55.6	92	50.3	
Parity	1033/521/512							0.87 ^d
0		561	54.3	286	54.9	275	53.7	

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1		317	30.7	154	29.6	163	31.8	
2		102	9.9	53	10.2	49	9.6	
≥ 3		53	5.1	28	5.4	25	4.9	
Marital status	1037/523/514							0.96 ^d
Married		520	50.1	261	49.9	259	50.4	
Cohabiting		476	45.9	241	46.1	235	45.7	
Single		27	2.6	13	2.5	14	2.7	
Other		14	1.4	8	1.5	6	1.2	
Place of residence	1037/523/514							0.54 ^d
Southern Finland		452	43.6	218	41.7	234	45.5	
Western Finland		402	38.8	212	40.5	190	37.0	
Eastern Finland		73	7.0	35	6.7	38	7.4	
Northern Finland		110	10.6	58	11.1	52	10.1	
University degree	1038/524/514	973	66.7	350	66.8	342	66.5	0.95 ^e
Low income	1030/520/510	82	8.0	44	8.5	38	7.5	0.57 ^e
Smoking status								
Smoking before pregnancy	1038/524/514	170	16.4	85	16.2	85	16.5	0.93 ^e
Smoking during pregnancy	1029/522/507	23	2.2	8	1.5	15	3.0	0.14 ^e
Chronic disease^f	1020/516/504	120	11.8	62	12.0	58	11.5	0.85 ^e
Special diet^g	1034/522/512	280	27.1	145	27.8	135	26.4	0.63 ^e
Gestational diabetes in current pregnancy^h	308/162/146	79	25.6	41	25.3	38	26.0	0.90 ^e

BMI, Body mass index

IQR, interquartile range

SD, standard deviation

^a Original number of participants (in the group)

^b Independent samples T-test

^c Mann-Whitney U test

^d Chi-squared test

^e Fisher's exact test

^f Type 1 diabetes (0.3%), type 2 diabetes (0.1%), cardiovascular disease (1.6%), coeliac disease (1.9%), irritable bowel syndrome (6.9%) or inflammatory bowel disease (1.3%).

^g Lactose-free (6.4%), milk-free (2.2%), gluten-free (5.2%), vegetarian (4.4%), or other diet such as grain-free diet or low fermentable oligo-, di-, monosaccharides and polyols (FODMAP) diet (12.4%).

^h Of the women, 7.6% were treated with metformin, 6.3% with insulin and 1.3% with both metformin and insulin.

Table 2. Efficacy of additional evidence-based health information delivered via the app in improving lifestyle during pregnancy between the standard app and enhanced app groups in all app users.

	Total n	All (n=386) ^a		Standard app group (n=206) ^a		Enhanced app group (n=180) ^a		P-value
		n, mean or median	%, SD or IQR	n, mean or median	%, SD or IQR	n, mean or median	%, SD or IQR	
Diet quality total scores								
Diet quality scores in early pregnancy	383/205/178	9.6	2.0	9.4	2.1	9.9	1.9	0.019 ^b
Diet quality scores in late pregnancy	214/115/99	9.8	2.0	9.8	1.9	9.9	2.2	0.59 ^b
Change in diet quality scores between early and late pregnancy	212/114/98	0.05	1.7	0.2	1.5	-0.08	1.8	0.31 ^b
Diet quality components								
Regular eating frequency (≤ 2 meals skipped per week) in early pregnancy	383/205/178	353	92.2	185	90.2	168	94.4	0.18 ^c
Regular eating frequency (≤ 2 meals skipped per week) in late pregnancy	213/114/99	195	91.5	107	93.9	88	88.9	0.22 ^c
Eating vegetables daily in early pregnancy	383/205/178	278	72.6	145	70.7	133	74.7	0.42 ^c
Eating vegetables daily in late pregnancy	213/114/99	157	73.7	78	68.4	79	79.8	0.063 ^c
Eating fruits and/or berries daily in early pregnancy	383/205/178	227	59.3	115	56.1	112	62.9	0.21 ^c
Eating fruits and/or berries daily in late pregnancy	213/114/99	147	69.0	78	68.4	69	69.7	0.88 ^c

pregnancy								
Eating vegetables, fruit and/or berries ≥ 5 portions/day in early pregnancy	383/205/178	172	44.9	85	41.5	87	48.9	0.15 ^c
Eating vegetables, fruit and/or berries ≥ 5 portions/day in late pregnancy	213/114/99	116	54.5	58	50.9	58	58.6	0.27 ^c
Weight								
Change in weight between early and late pregnancy, kg	215/112/103	9.3	4.7	9.5	5.0	9.2	4.3	0.56 ^b
Weekly weight gain rate, kg	215/112/103	0.5	0.2	0.5	0.2	0.4	0.2	0.22 ^b
Physical activity scores								
MET scores in early pregnancy	382/204/178	7.5	3.0 – 12.0	7.5	3.0 – 15.0	7.5	3.0 – 12.0	0.56 ^d
MET scores in late pregnancy	210/113/97	3.0	0.5 – 12.0	3.0	0.3 – 8.4	4.8	1.2 – 12.0	0.074 ^d
Change in MET scores between early and late pregnancy	208/112/96	-1.0	-9.0 – 0.0	-1.8	-10.4 – 0.0	-0.38	-8.2 – 0.0	0.38 ^d

IQR, interquartile range

SD, standard deviation

^a Original number of participants (in the group) among all app users

^b Independent samples T-test

^c Fisher's Exact test

^d Mann-Whitney U test

Table 3. Use of the health app in all participants and according to their allocation into standard app and enhanced app groups.

	Total n	All (n=1038) ^a		Standard app group (n=524) ^a		Enhanced app group (n=514) ^a		P-value
		n, mean or median	%, SD or IQR	n, mean or median	%, SD or IQR	n, mean or median	%, SD or IQR	
		Participants that created an account in the app	1038/524/514	789	76.0	403	76.9	
App users^b	1038/524/514	386	37.2	206	39.3	180	35.0	0.16 ^c
Frequent app users^d								
Of the app users	386/206/180	193	50.0	98	47.6	95	52.8	0.36 ^c
Of all women	1038/524/514	193	18.6	98	18.7	95	18.5	0.94 ^c
Occasional app users^e								
Of the app users	386/206/180	193	50.0	108	52.4	85	47.2	0.36 ^c
Of all women	1038/524/514	193	18.6	108	20.6	85	16.5	0.094 ^c
App non-users^f	1038/524/514	652	62.8	318	60.7	334	65.0	0.16 ^c
Number of recordings made in the app over the study period	386/206/180	59	19 – 294, range 2 – 4651	57	18 – 250, range 3 – 4651	59	21 – 340, range 2 – 4614	0.45 ^g
Duration of the app use in total (weeks)	386/206/180	4.7	1.1 – 15.6, range 0.1 – 35.1	4.0	1.0 – 15.7, range 0.1 – 35.3	5.3	1.1 – 15.1, range 0.1 – 34.9	0.70 ^g
Number of the most frequently	386/206/180							

made recordings in the app**(% of all recordings)**

Meal	27941	23.2	14300	24.0	13641	22.4	<0.001 ^c
Water	18885	15.7	9606	16.1	9279	15.2	<0.001 ^c
Fruits	12371	10.3	6162	10.3	6209	10.2	0.39 ^c
Vegetables	11657	9.7	5782	9.7	5875	9.6	0.73 ^c
Mood	11081	9.2	5523	9.3	5558	9.1	0.39 ^c
Exercise (minutes)	8185	6.8	4025	6.7	4160	6.8	0.61 ^c
Sleeping (minutes)	7371	6.1	3598	6.0	3773	6.2	0.26 ^c
Quality of sleep	6985	5.8	3343	5.6	3642	6.0	0.006 ^c
Coffee	5176	4.3	2147	3.6	3029	5.0	<0.001 ^c
Weight	2873	2.4	1476	2.5	1397	2.3	0.038 ^c
Exercise (steps)	2651	2.2	1311	2.2	1340	2.2	1 ^c
Exercise (distance)	1152	1.0	539	0.9	613	1.0	0.071 ^c
Blood glucose	1021	0.9	507	0.9	514	0.8	0.90 ^c

How many app users recorded the following lifestyle factors in the app at least once?

386/206/180

Meal	315	81.6	168	81.6	147	81.7	1 ^c
Water	336	87.0	186	90.3	150	83.3	0.049 ^c
Fruits	344	89.1	185	89.8	159	88.3	0.74 ^c
Vegetables	340	88.1	184	89.3	156	86.7	0.44 ^c

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Mood	346	89.6	190	92.2	156	86.7	0.094 ^c
Exercise (minutes)	311	80.6	162	78.6	149	82.8	0.37 ^c
Sleeping (minutes)	326	84.5	178	86.4	148	82.2	0.26 ^c
Quality of sleep	339	87.8	183	88.8	156	86.7	0.54 ^c
Coffee	255	66.1	131	63.6	124	68.9	0.28 ^c
Weight	314	81.3	175	85.0	139	77.2	0.066 ^c
Exercise (steps)	71	18.4	34	16.5	37	20.6	0.36 ^c
Exercise (distance)	69	17.9	37	18.0	32	17.8	1 ^c
Blood glucose	51	13.2	25	12.1	26	14.4	0.55 ^c

IQR, interquartile range

SD, standard deviation

^a Original number of participants (in the group)

^b Made at least one recording in the app

^c Fisher's exact test

^d Recorded for at least 4.7 weeks

^e Recorded at least once but for less than 4.7 weeks

^f No recordings in the app

^g Mann-Whitney U test

Table 4. Factors characterizing the frequency of using the app.

	Total n	All (n=1038) ^a		Non-user (n=652) ^a		Occasional user (n=193) ^a		Frequent user (n=193) ^a		P-value
		n	%	n	%	n	%	n	%	
		or mean	or SD	or mean	or SD	or mean	or SD	or mean	or SD	
Age, years	1033/651/190/192	29.4	4.0	29.2	4.2	29.7	3.5	29.4	3.9	0.41 ^b
Pre-pregnancy BMI	1035/650/192/193									0.030 ^c
Underweight or normal weight		656	63.4	403	62.0	115	59.9	138	71.5	
Overweight or obese		379	36.6	247	38.0	77	40.1	55	28.5	
Parity	1033/648/192/193									0.005 ^c
1 st child		561	54.3	331	51.1	106	55.2	124	64.3	
2 nd child or more		472	45.7	317	48.9	86	44.8	69	35.8	
Marital status	1037/652/192/193									0.007 ^c
Married		520	50.1	304	46.6	102	53.1	114	59.1	
Not married		517	49.9	348	53.4	90	46.9	79	40.9	
Place of residence	1037/651/193/193									0.80 ^c
Southern Finland		452	43.6	281	43.2	83	43.0	88	45.6	
Western Finland		402	38.8	256	39.3	70	36.3	75	39.4	
Eastern Finland		73	7.0	48	7.4	15	7.8	10	5.2	
Northern Finland		110	10.6	66	10.1	25	13.0	19	9.8	
Education	1038/652/193/193									<0.001 ^c
Lower education		346	33.3	246	37.7	49	25.4	51	26.4	

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University education		692	66.7	406	62.3	144	74.6	142	73.6	
Yearly income, €	1030/646/191/193									0.44 ^c
<20.000		82	8.0	58	9.0	11	5.8	13	6.7	
20.000 – 40.000		280	27.2	185	28.6	46	24.1	49	25.4	
40.001 – 60.000		276	26.8	169	26.2	56	29.3	51	26.4	
> 60.000		392	47.3	234	36.2	78	40.8	80	41.5	
Work position	866/540/168/158									0.32 ^c
Worker (manual worker)		478	55.2	307	56.9	95	56.6	76	48.1	
Employee (clerical worker)		172	19.9	107	19.8	35	20.8	30	19.0	
Managerial employee/manager		171	19.8	99	18.3	31	18.5	41	26.0	
Entrepreneur		45	5.2	27	5.0	7	4.2	11	7.0	
Smoking status										
Smoking before pregnancy	1038/652/193/193	170	16.4	119	18.3	30	15.5	21	10.9	0.049 ^c
Smoking during pregnancy	1029/650/192/187	23	2.2	13	2.0	6	3.1	4	18.2	0.65 ^c

BMI, Body mass index

SD, standard deviation

^a Original number of participants (in the group)

^b One-way ANOVA

^c Chi squared test

Table 5. Efficacy of the app use in improving lifestyle during pregnancy in all participants and in app non-users, occasional users and frequent users.

	Total n	All (n=1038) ^a		Non-user (n=652) ^a		Occasional user (n=193) ^a		Frequent user (n=193) ^a		P-value
		n or median	% or IQR	n or median	% or IQR	n or median	% or IQR	n or median	% or IQR	
Diet quality total scores										
IDQ scores in early pregnancy	1029/646/192/191	9.0	8.0 – 11.0	9.0 ()	8.0 – 11.0	9.3	8.0 – 11.0	10.0	8.0 – 11.0	0.002 ^b
IDQ scores in late pregnancy	384/171/69/144	10.0	9.0 – 11.0	10.0	9.0 – 11.0	10.0	8.1 – 11.0	10.0	9.0 – 11.0	0.41 ^b
Change in IDQ scores between early and late pregnancy	382/171/68/143	0.0	-1.0 – 1.0	0.0	-1.0 – 1.0	0.0	-1.0 – 1.0	0.0	-1.0 – 1.0	0.88 ^b
Diet quality components										
Regular eating frequency (≤ 2 meals skipped per week) in early pregnancy	1029/646/192/191	921	89.5	568	87.9	176	91.7	17	92.7	0.10 ^c
Regular eating frequency (≤ 2 meals skipped per week) in late pregnancy	384/171/69/144	349	90.9	154	90.1	65	94.2	130	90.3	0.57 ^c
Eating vegetables daily in early pregnancy	1029/646/192/191	712	69.2	434	67.2	136	70.8	142	74.4	0.15 ^c
Eating vegetables daily in late pregnancy	384/171/69/144	279	72.7	122	71.4	49	71.0	108	75.0	0.73 ^c
Eating fruits and/or berries daily in early pregnancy	1029/646/192/191	556	54.0	329	50.9	108	56.3	119	62.3	0.017 ^c
Eating fruits and/or berries daily in late pregnancy	384/171/69/144	261	68.0	114	66.7	38	55.1	109	75.7	0.009 ^c

pregnancy

Eating vegetables, fruit and/or berries ≥ 5 portions/day in early pregnancy	1029/646/192/191	437	42.5	265	41.0	83	43.2	89	46.6	0.38 ^c
Eating vegetables, fruit and/or berries ≥ 5 portions/day in late pregnancy	384/171/69/144	211	54.9	95	55.6	33	47.8	83	57.6	0.39 ^c

Weight

Gestational weight gain, kg	383/168/73/142	9.0	6.0 – 12.0	8.0	5.0 – 11.0	9.0	5.0 – 11.0	9.0	6.0 – 12.0	0.083 ^b
Weekly weight gain rate, kg	381/167/73/141	0.4	0.3 – 0.6	0.4	0.3 – 0.6	0.5	0.3 – 0.6	0.4	0.3 – 0.6	0.73 ^b

Physical activity

MET scores in early pregnancy	1031/649/191/191	7.5	3.0 – 15.0	7.5	3.0 – 15.0	7.5	2.0 – 12.0	7.5	3.0 – 18.8	0.056 ^b
MET scores in late pregnancy	376/167/67/142	3.0	0.5 – 12.0	3.0	0.8 – 7.5	4.8	0.8 – 12.0	3.0	0.5 – 12.0	0.80 ^b
Change in MET scores between early and late pregnancy	372/165/67/140	-1.8	-8.80 – 0.0	-2.5	-7.5 – 0.0	0.0	-4.8 – 1.5	-2.4	-9.3 – 0.0	0.082 ^b

IQR, interquartile range

^a Original number of participants (in the group)^b Kruskal-Wallis test^c Chi-squared test