A m-health intervention in the maternal care pathway: protocol for the impact evaluation of hAPPyMamma

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Abstract

Background: M-health has a great potentiality in both improving quality and efficiency of care, and in increasing health literacy and empowerment of patients-users. There are several studies related to the introduction on m-health tools for supporting pregnancy and the post-natal period, with promising but not still rigorously evaluated impacts. This article contributes to the literature, by presenting an m-health intervention (the mobile app called “hAPPyMamma”) applied in the maternal and child care of a high-income country (in a pilot area of Tuscany Region, Italy) and the methods adopted for evaluating its impact.

Objective: The final aim of the introduction of this m-health app in the maternal care pathway is to promote the health of pregnant women and of their children and to improve their experience of care.

Methods: This study is based on a quasi-experimental design that compares two groups: women who use the app (intervention group) and women who do not use the app (control group). The data concerning the measures of the maternal health literacy and the empowerment are collected prospectively in order to be able to perform a difference in difference analysis. In the post-partum period also data on women’s experience in the maternal care pathway are collected from both groups and data on the experience of the hAPPyMamma use are collected only within the intervention group. The organisational impact is evaluated through a quantitative and qualitative survey addressing professionals and managers of the maternal care pathway involved in the intervention.

Results: The recruitment of the two samples was carried out with the same procedure in 2017, and was subsequent: first, the control group, and after some months, the intervention group. 177 women were enrolled in the control group; out of them, 170 answered to the first web questionnaire and 114 to second one. 150 women were enrolled in the intervention group; out of them, 100 women answered the first web questionnaire and 90 the second one. Data collection was completed in April 2018. Data analysis is underway.

Conclusions: This study evaluates the implementation of the m-health intervention hAPPyMamma and describes its impact at individual and organisational level, in terms of the improvement of maternal health literacy, the access to and the utilisation of healthcare services during the maternal care pathway. This study contributes to define the potential role of this m-health tool in maternal care pathway in Tuscany Region and consequently in the Italian context, and the possible extension of its implementation.

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A m-health intervention in the maternal care pathway: protocol for the impact evaluation of hAPPyMamma

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Abstract

Background

M-health has great potential to both improve the quality and efficiency of care, and to increase health literacy and empowerment of patients-users. There are several studies related to the introduction of m-health tools for supporting pregnancy and the post-natal period, with promising but not yet rigorously evaluated impacts. This article presents the protocol for evaluating an m-health intervention (hAPPyMamma) applied in the maternal and child care pathway of a high-income country (in a pilot area of Tuscany Region, Italy).

Objectives

The protocol describes hAPPyMamma and the methods for evaluating its impact, including the points of view of women and practitioners. The research hypothesis is that the use of hAPPyMamma will facilitate a more appropriate use of available services, a better care experience for women, and an improvement in the maternal competencies of the women using the app compared to the control group. The protocol also includes analysis of the organisational impact of the introduction of hAPPyMamma in the maternal pathway.

Methods

A pre–post quasi-experimental design with a control group is used to undertake difference in differences analysis for assessing the impact of the m-health intervention from the mothers' point of view. The outcome measures are improvement of maternal health literacy and empowerment and experience in the maternal care pathway of the control and intervention groups of sampled mothers. The organisational impact is evaluated through a quantitative and qualitative survey addressing professionals and managers of the maternal care pathway involved in the intervention.

Results

Following study recruitment, 177 women were enrolled in the control group and 150 in the intervention group, with a participation rate of 97-98%. The response rate was higher in the control group compared to the intervention group (96% vs 67%), though the intervention group had less respondent loss at the post-survey (10% compared to 33% of the control group). Data collection from the women sampled was completed in April 2018, while that from professionals and managers is underway.

Conclusions

The study helps consolidate evidence of utility of m-health interventions for maternal and child care in developed countries. This paper presents a protocol for analysing the potential role of hAPPyMamma as an effective m-health tool for improving the maternal care pathway at individual and organisational levels, and consequently helps to understand whether and how to scale up this intervention, with a local, national and international scope of application.

Keywords: m-health, maternal care pathway, impact evaluation, quasi-experimental study

Introduction

Background

Mobile health (hereafter “m-health”) can play a disruptive role in transforming health promotion and healthcare services provision. M-health refers to health-related practice supported by mobile and wireless devices, such as mobile phones, smartphones and tablets, including mobile applications (hereafter “apps”) [1]. The growing spread of mobile devices has pushed the use of apps providing digital services, including for healthcare.

M-health has great potential to both improve quality and efficiency of care [2, 3], and to increase health literacy and empowerment of patients-users [4]. Using m-health apps, people can manage their health and wellbeing more actively and consciously [3]. Due to its characteristics of ubiquity and the possibility of personalization, it is expected to be a powerful tool of patient-centred care.

Nevertheless, there is contradictory evidence about m-health intervention impacts on health promotion practice and health outcomes [5, 6, 7, 8]. There are several studies focusing, in particular, on the introduction of m-health tools for supporting pregnancy and the post-natal period, with promising but not yet rigorously evaluated impacts [9]. The evidence of effectiveness in behavioural change are also inconsistent, with both ineffective [10] and effective interventions [11, 12] targeted to pregnant women and mothers. Furthermore, there is evidence of demonstrated positive outcomes from m-health tools for pregnant women and future mothers, but also of the difficulties related to the routine integration of m-health tools into established prenatal and new-born health services [13]. Nonetheless, it is worth pointing out that most of the research studies on m-health interventions in the field of maternal, neonatal, and new-born care have been undertaken in low- and middle-income countries [14-29].

This protocol presents a m-health intervention for maternal and child care in a high-income country, including the methods adopted for evaluating its impact at individual and organisational levels.

Study and policy context concerning m-health and maternal care pathway

The context of this study is the Region of Tuscany (Italy), which shows characteristics of e-health diffusion in line with both the national and wider European context [30, 31].

Within the framework of the Italian public healthcare system ensuring universal healthcare coverage, maternal care is guaranteed for all women free of charge as an essential level of care [32, 33]. Although this includes services provided by hospitals and family care centres along the entire maternal journey until the post-partum period, the majority of women prefer to be supported by a private gynaecologist during pregnancy [34]; this may limit communication of the publicly available community services offered to pregnant women and new mothers. To standardize the prenatal visits and treatments within its territory, Tuscany Region provided women with a pregnancy booklet, delivered by a midwife at the family care centre. Despite such efforts to strengthen the maternal care pathway, some critical issues remain unresolved in Tuscany [35-38]. A first problem concerns the lack of coordination between services, especially where the maternal care pathway requires integration between Local Health Authorities and Teaching Hospitals. A second issue is related to the communication channels: Tuscan women clearly expressed the preference to be informed using Information and Communication Technology (ICT) such as text messages or emails [35]. A third issue concerns poorer healthcare service use by specific categories, such as foreign women and those

with a low level of education [36]. Due to their weaker health literacy, these groups are often the least likely to exercise choice and to have a direct and appropriate relationship with healthcare services, and consequently, equal access to antenatal and postnatal care [39]. A final issue regards infant vaccination coverage, which in 2016 was under 90% for measles [40].

To address the abovementioned weaknesses and gaps, Tuscany financed and promoted the development and pilot study of the mobile app hAPPyMamma in a Local Health Authority (LHA). hAPPyMamma was designed as a supportive tool for women and professionals who can provide women with information about maternal care pathway and its services, also targeted to specific categories (such as low-income women). This may increase the opportunity for contact and interaction, as well as the womens' self-management, and can facilitate disadvantaged groups in accessing and using services [41].

Design and implementation of the mobile app hAPPymamma

The mobile app offers different functionalities. From the homepage, gestational age (during pregnancy) or newborn age (in post-partum) are addressed with personalised messages (Figure 1). It includes a digital translation of the pregnancy booklet and infant vaccination calendar into the planner within the app (Figure 2), including alert mechanisms to notify women about visits and diagnostic tests to reserve or, if reserved, to attend.

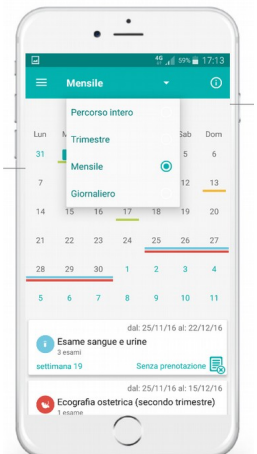
Women can digitally book, directly from the app, the three obstetric ultrasounds (the first visit in pregnancy and the post-partum visit) (Figure 3), which are the mandatory touchpoints of the maternal care pathway in Tuscany.

hAPPyMamma contains information on health promotion and prevention, as well as on the healthcare services concerning pregnancy, childbirth and post-partum, divided into thematic sections (Figure 4). It also proactively shows information through pop-up messages, based on data reported by women (i.e. smokers will receive pop-up messages on the specific topic of smoking during pregnancy).

hAPPyMamma includes a section with logistic details of primary care and hospital services along the maternity care pathway, with geo-referring system (Figure 5). It first presents services and providers related to the woman's residence area. Additionally, hAPPyMamma is integrated with the regional mobile app that allows access to the personal health record developed by the Tuscan Regional Health System. Finally, women using the app can provide direct feedback and answer questionnaires, proposed by the app, to evaluate their experience in the maternity care pathway.

The design of hAPPyMamma was user-driven, as described above, and its development was shared with the professionals involved at both the primary care and hospital level, and in both the maternal and child care area. It involved the researchers of the Sant'Anna School, who facilitated the process in the app design and evaluated the results of this innovation.

Figure 1. identification of or newborn age week-by-week;



hAPPyMamma homepage: gestational age (during pregnancy) (in post-partum); specific messages next appointments memo.

Figure 2. **hAPPyMamma agenda: digitization**

of pregnancy booklet and infant vaccination calendar in the app planner, with different visualization options and alert mechanisms.

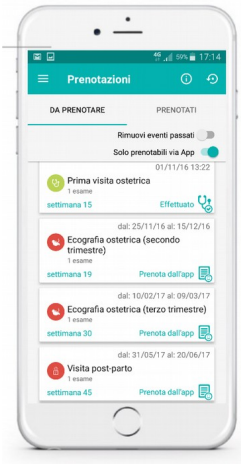


Figure 3. hAPPyMamma e-booking: visits and tests e-booking via hAPPyMamma; integration into the app planner and synchronisation with the LHA booking system.

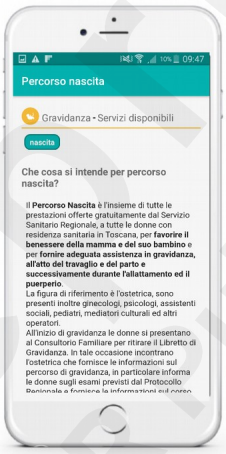


Figure 4. hAPPyMamma information repository: storage of information (in FAQ format) validated by professionals, on health promotion, prevention, healthcare services concerning pregnancy, childbirth and post-partum; information proposed proactively via pop-up messages.

Figure 5. hAPPYMamma facilities repository: storage of information on facilities (family care centers and delivery hospitals), with logistic details, services provided and georeferrring system embedded.

Objectives

The aim of the study reported in this protocol is to evaluate whether and to what extent the mobile app hAPPyMamma is able to increase (i) maternal health literacy (MHL) and empowerment of women, (ii) access to and utilisation of healthcare services during the maternal-care-pathway. Our hypothesis is thatimplementation of the m-health solution will bring a positive impact on the maternal care pathway, in terms of a more appropriate use of the available services, a better experience for women, and an improvement in the maternal competencies of women using hAPPyMamma. To meet the above objectives, the study proposes to compare pre and post differences for the control group versus the intervention group using hAPPyMamma.

Moreover, the protocol includes an analysis of the use of hAPPyMamma for the intervention group, and an analysis of the organisational impact of the introduction of the app in the maternal pathway from the professionals' perspectives.

Methods

Impact evaluation of the hAPPyMamma m-health intervention is provided in detail below.

Study design

This study used a pre-post quasi-experimental design that compares two groups: women who use the app (intervention group) and women who do not use the app (control group), in order to assess the impact of the use of hAPPyMamma in the maternal care pathway. The manipulation of the independent variable (app use) is done by recruiting consequentially the two groups: the control group before that the app is available on the app stores; the experimental group when the app has been introduced into the maternal-care pathway. The Ethical Committee of the LHA where the m-health intervention is implemented has approved the research protocol (Authorization n. 42379 signed by Ethical Committee the 13/07/2016 and registered with the approval number n. 0133972 of 03/08/2016).

The choice of not randomising the samples using and not using the mobile app is in line with the ethical principles. Indeed, the mobile app can represent a potential tool to improve the quality of the maternity care pathway and the randomisation of women could have brought unfair advantages to women who use the app compared to the others. Therefore the choice of a quasi-experimental study design addresses also this ethical principle.

The data concerning the measures of maternal health literacy and empowerment are collected prospectively through a web pre-post survey, enabling difference in difference analysis to assess the impact of the m-health intervention [42]. In particular, there are two data collection moments through the web platform. The first data collection (pre-survey) is carried out at the beginning of the maternal care pathway, when women receive the pregnancy booklet, corresponding to the beginning of the pregnancy. The second data collection (post-survey) is implemented around 6 months after childbirth in the postpartum period, when data on women's experience in the maternal care pathway are also collected. This second survey questionnaire contains also a section reserved for the intervention group on their experience of hAPPyMamma use.

The organisational impact is evaluated through a quantitative and qualitative survey and in-depth interviews addressing professionals and managers of the maternal care pathway in the LHA and Teaching Hospital involved. Both data collection methods focus on the perceived changes the

practitioners identify in their job activities due to the m-health intervention. The survey uses a web questionnaire with close-ended and open-ended questions, in order to measure and assess practitioners' perceptions and opinions on hAPPyMamma impact through rating questions and narratives. The survey results are discussed with some practitioners during the in-depth interviews. Considering that the organisational impact can be better evaluated through a mid-term evaluation, this component of the study protocol is planned to be implemented after implementation of the data collection with mothers.

Study population and sample size

The sample size for the pre-post survey addressing mothers was estimated with respect to differences concerning some key measures considered within the study, namely MHL level and other experience measures such as access to maternal care services and satisfaction with the maternal care received. We determined the sample size required to detect a 10% difference between the two groups concerning the key measures considered within the study, when this difference genuinely exists in the populations of the mothers, with a power of 80% and an alpha error of 5%. With these parameters, a sample size of 300 pregnant women, divided equally between the control and intervention groups, was considered appropriate for a study population of around 2,000 births in the pilot LHA yearly.

The quantitative and qualitative survey focusing on the organisational impact of the m-health intervention uses a convenience sample of professionals and managers working in the LHA and Teaching Hospital of the study area. All midwives, obstetricians, paediatric doctors and other professionals of the maternal care pathway are invited to fill in the web questionnaire. The results of this data collection are discussed with 15 practitioners during in-depth interviews

Eligibility criteria

All women receiving the pregnancy booklet in the family care centres of the three districts of the pilot LHAs involved in the study are included during the recruitment period. The only exclusion criteria is not speaking Italian, because the app does not have the multi-language function activated during the experimentation phase. Finally, women without smartphones are not able to use hAPPyMamma and thus do not participate in the study within the intervention group.

Outcomes

The study objectives are addressed in the following ways.

- To measure the difference in the MHL and empowerment improvement between the control and intervention groups

Key outcomes of the study concern MHL and empowerment of women involved in the maternity pathway, which may be particularly improved in the intervention group thanks to the use of the mobile app hAPPyMamma. In order to measure them, some items of internationally validated tools are used [43-45]. Table 1 shows the dimensions included in the MHL construct: critical, functional, self-efficacy and social capital. The first three dimensions of MHL focus mainly on underlining the competence of mothers for promoting and protecting their health and that of their children, as well as orienting among health information and services. The fourth dimension concerns social capital that can be considered both a demonstration and a consequence of MHL. In order to define the MHL items for the pre-post questionnaire, two different researchers translated the items from the international scales, compared and discussed together the two different translations, and finally identified a shared version of the Italian items.

Empowerment is evaluated in our study in terms of self-efficacy on breastfeeding and duration of breastfeeding (total and exclusive). These measures that are internationally considered a proxy indicator of mother's empowerment can be positively affected by the more direct and easy access to information on breastfeeding through the app.

- To evaluate the experience of the control and intervention groups in the maternal care pathway

The experience of women in the maternal care pathway is measured through a selection of the questions included in the validated questionnaires that have been used periodically in Tuscany Region to evaluate the users' perspective in the maternal care pathway [35, 36]. As shown in the Table 1, this dimension of experience concerns the use of health services during the maternal care pathway, such as prenatal care, antenatal classes, post-partum care, and they explore particularly the difficulties in the access to and orientation among the health services of the maternal care pathway. The questions focus also on the perceived quality of the maternal care pathway and the willingness to recommend its services to friends and family members. The use of the same survey tool ensures continuity in the research approach and the possibility to assess the trend in the outcomes measured.

- To analyse the use of hAPPyMamma for the intervention group only

A specific section concerning the experience of the hAPPyMamma use and its usability is introduced in the post-survey questionnaire for the intervention group only (Table 1). The first dimension explores mainly the duration and frequency of use of hAPPyMamma, the perceived utility of the hAPPyMamma functionalities, and the opinions of mothers concerning the comparison of hAPPyMamma with other apps related to maternity. The usability includes the principal criteria included in the scales used at the international level [46-49], such as learnability, memorability, understandability, attractiveness, errors, efficiency, quality, and satisfaction. Moreover, some questions focussing on the mothers' interest for ICT services are introduced in the post-survey questionnaire; these investigate mothers possible interest in receiving - by email, message or app - information and reminder on visits and exams, antenatal classes, post-partum services; information on healthy lifestyles during pregnancy, health information records for pregnancy, delivery and post-partum, communication with family paediatrician. They are submitted both to intervention and control groups, in order to assess the interest also of mothers who are not using the m-health solution. The intervention group has an additional option for answering the above-mentioned questions, namely that they already receive information and reminders via hAPPyMamma.

- To describe the organisational impact of the introduction of the app hAPPyMamma in the maternity pathway from the professionals' perspectives.

The organisational impact is assessed through a web survey and in-depth interviews with the professionals and managers of the maternal care pathway (midwives, obstetricians, neonatal doctors), focussing on the aspects of the experimental use of the mobile app affecting the healthcare process. In particular, the web survey and interviews explore their expectations before m-health solution implementation, their perceived difficulties and worries, feelings of uncertainty, fear of replacement, desire to innovate and the resistance to change that may characterise the opinions of the involved professionals. The descriptive analysis of the questionnaire allows elucidation of the experience of professionals and managers regarding the m-health intervention. These results represent the basis of the discussion with some professionals and managers during the in-depth interviews. The implementation of web survey and in-depth interviews after the end of

the experimentation allow description of the impact of hAPPyMamma on healthcare services and practices from the point of views of professionals, with a certain period of distancing from the m-health intervention to better appreciate its organizational impact.

Table 1. Dimensions included in the pre-post survey questionnaires addressing sampled women in the maternal care pathway

Dimensions	Description	Control group		Intervention group	
		Pre-survey	Post-survey	Pre-survey	Post-survey
Maternity pathway expectations	Expectations about pregnancy, delivery and post-partum (1 item)	X		X	
MHL - Critical	Search of different sources of information, check of validity and reliability of information, use of information to take decisions on own health (7 items)	X	X	X	X
MHL - Functional	Ability to understand health information, difficulty in reading and interpreting health information materials, self-confidence to fill in modules with health information (4 items)	X	X	X	X
MHL - Self-efficacy	Self-confidence to follow health indications, self-confidence to be autonomous in taking care of own child, capability to identify different positive solutions facing obstacles (4 items)	X	X	X	X
MHL - Social capital	Support from someone in case of concerns or doubts on own conditions, continuity of social life after pregnancy (2 items)	X	X	X	X
Intention to breastfeeding	Expectations of breastfeeding and its duration (2 items)	X		X	
Breastfeeding – Empowerment	Total breastfeeding, exclusive breastfeeding and its duration (3 items)		X		X
Experience in maternal care pathway	Booking of exams during pregnancy, awareness of prenatal diagnosis tests, sources of information on prenatal diagnosis tests, attendance at antenatal classes, difficulties in accessing health services during pregnancy, awareness on facing labour and delivery, use of health services after delivery, orientation difficulties in maternal care pathway, satisfaction of the maternal care received, suggestions on maternal care pathway improvement (14 items)		X		X
Type of healthcare during pregnancy and delivery	Professional and service involved in the pregnancy follow up, number of visits and ultrasounds, characteristics of pregnancy and delivery (8 items)		X		X
Interest for ICT services	Information and reminders for visits and exams, antenatal classes, post-partum services, information on healthy lifestyle during pregnancy, health information records for pregnancy, delivery and post-partum, communication with family paediatrician – by different ICT tools (8 items)		X		X
Experience of hAPPyMamma use	Duration and frequency of use, habits in smartphone and internet use, comparison with other apps concerning maternal care, utility of different app functionalities, suggestions to improve the app use (11 items)				X
Usability of hAPPyMamma	Learnability, memorability, understandability, attractiveness, errors, efficiency, evaluation of quality, satisfaction in terms of willingness to recommend, (15 items)				X
Socio-demographic characteristics	Age, citizenship, education level, employment status, gestational age, number of children (6 items)	X		X	

Statistical and qualitative data analysis

Descriptive statistics are used to characterize the study population to give an overview of the two groups concerning demographic characteristics and use of services during pregnancy, birth and post-partum.

The impact of the app hAPPyMamma on the MHL is evaluated through a difference in differences analysis, which allows measuring the difference in changes pre and post intervention between the two groups. In particular, the panel data of the study are used to measure the differences, between the treatment and control group, of the changes in the outcome variable (MHL) that occur over time. In particular, we calculate the effect of the use of hAPPyMamma (i.e., an explanatory variable or an independent variable) on MHL (i.e., a response variable or dependent variable) by comparing the average change over time in the outcome variable for the treatment group, and the average change over time for the control group. We also verify the impact of the use of hAPPyMamma on the sub-dimensions of MHL.

Other multivariate analyses of variance are carried out in order to evaluate the empowerment, related to breastfeeding results, and the experience of women in the maternity pathway, specifically comparing the control and intervention groups.

Descriptive statistics and multivariate models are used also for analysing the experience in the hAPPyMamma use and its usability.

All the statistical analyses are performed using SAS and Stata software.

Descriptive statistics are performed for the web questionnaires completed by professionals and managers. These results are presented to key practitioners involved in the depth-interviews. Qualitative analysis of the in-depth interviews are performed by using QSR NVivo software. After importing the narrative answers to the web questionnaire and the transcriptions of the in-depth interviews, coding data process is implemented by two researchers. Content analysis is carried out in order to identify emerging themes and patterns of the perception of professionals on the organisational impact of hAPPyMamma in the maternal care pathway [50].

Results

Recruitments of the two samples of mothers (control and intervention groups) were carried out in sequence. The data collection started at the beginning of 2017, with the control group. In May 2017, hAPPyMamma was made available on app stores, and the recruitment of intervention group started. Both groups were recruited by using the same procedures. At the time of receiving the pregnancy booklet, women were informed about the study by midwives. Women who decided to participate signed a consent form, leaving their email address. For the control group, we sent by e-mail an invitation to fill-in the first web questionnaire at the beginning of the maternity pathway, while the intervention group received directly the invitation concerning the first web questionnaire from the app. The invitation for the second questionnaire was sent by e-mail to both groups, with the intervention group having also the possibility to access the web questionnaire from the app.

The participation rate was high for both the control and the intervention groups (around 97-98%), since the consensus for attending the study was given by 177 women in the former, and by 150 women in the latter. The response rate was different between the two groups: 96% in the control

group and 67% in the intervention group, with 170 women answering the first questionnaire in the control group, and 100 women in the intervention group. The difference in respondents' loss in follow-up questionnaires was reversed: 33% in the control group, and only 10% in the intervention group, which correspond respectively to 114 and 90 participants for the second web questionnaire. Data collection was completed in April 2018.

Data analysis is currently underway, as well as the data collection with professionals and managers.

Discussion

This paper provides the protocol to evaluate the implementation of an m-health intervention and its impact at individual and organisational levels, in terms of the improvement of maternal health literacy, mothers' empowerment, and access to and utilisation of healthcare services in the maternal care pathway. We collect data to describe the experimental use of the app hAPPyMamma and report on benefits accruing to the mothers using the app. This study is innovative in the Italian context, and compared with other interventions worldwide. The m-health intervention analysed is realised thanks to collaboration between university researchers and health professionals in maternal care, and is promoted by the Regional Health Authority with the aim of improving the quality of the maternal care pathway. Therefore, the study results assume an institutional perspective and will provide insights on the impact of hAPPyMamma use from the organisational as well as the user perspectives, and on the perceptions on the provision of several services in the maternal care pathway through this m-health channel.

Interviews with key professionals of the maternal care pathway will help to deeply understand their point of view, alongside insights emerging from the quantitative and qualitative web survey. This will contribute to identifying and explaining factors positively and negatively affecting the implementation and deployment of hAPPyMamma from their perspectives, and those that may facilitate or inhibit the normalisation of the innovative tool within the maternal care pathway.

The findings of this study will be relevant for the academic community, and for policy-makers and practitioners. First, there is scarce empirical evidence of the real potential of m-health in improving women's' access to care, their literacy and self-management skills, and quality of services along the maternal pathway [9]. This is particularly true for western countries, because literature focuses on the impact of technologies in developing countries [14-29]. In the high-income countries, technology-supported interventions targeted to pregnant women and new mothers are often aimed at improving their lifestyle-related behaviours [9, 51]. Conversely, current critical circumstances that impose social-distancing and limit physical access to care have highlighted the need for evidence-based technologies to be introduced to support digital and at distance healthcare services' in time of crisis, to be maintained in normal times. This is the second key point that supports the need for evidence on effectiveness of m-health services for women in the maternal pathway in developed countries. Service innovation is urgent in healthcare [52], and hAPPyMamma is an innovative way of providing women-centered services along a pathway, allowing also the evaluation of several different outcomes.

There are several strengths in the design of this study. Its methodological approach as a quasi-experimental study allows overcoming the limitations of observational studies in measuring the effectiveness of interventions and their impact at the individual and organisational levels [53, 54]. It is an appropriate method for evaluating policies or interventions, such as hAPPyMamma, collecting data before the recipients are exposed to policy or intervention activities [55]. The results of the

study contribute to verify the possibilities and potential of the scaling up of the m-health intervention.

The study faces some potential methodological and practical challenges. The non-randomisation of the sample, which is an important aspect from the ethical point of view, represents a weakness of the study. Indeed, the non-contemporaneous recruitment of the intervention and control groups does not allow excluding the possibility of influencing factors due to environmental or organisational context [54, 56].

Moreover, the differences in response rate and loss to follow up among maternal samples have to be taken into account, and data analysis will verify if these affect the results [57].

In conclusion, this study contributes to defining the potential role of the m-health intervention hAPPyMamma in the maternal care pathway. The findings of this study could provide valuable insights on the benefits of the hAPPyMamma use for the women's experience in maternal care pathways. Therefore, this study could significantly support analysis to understand if scaling up hAPPyMamma implementation from the pilot area to the Tuscany Region, as well as to the entire country, would be beneficial. As anticipated, the findings that will result from the evaluation of this m-health intervention will also provide useful insights for supporting the introduction of mobile-based innovations in maternal and new-born care pathways in other (developed as well as developing) countries.

List of abbreviations

ICT Information and Communication Technology
LHA Local Health Authority
MHL Maternal Health Literacy

Declarations

Ethics approval and consent to participate

Ethical approval was acquired from the Ethical Committee of the Local Health Unity involved in the study (ethical committee of the North West Local Health Authority in Tuscany Region, Authorization n. 42379 signed by Ethical Committee the 13/07/2016 and registered with the approval number n. 0133972 of 03/08/2016). Written informed consent was requested to women to participate in the study.

Consent for publication

Not applicable because the manuscript does not contain any individual person's data.

Availability of data and material

Data from the study will be made available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests or conflict of interest.

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Authors' contributions

MB coordinated the design and implementation of the mobile app hAPPyMamma. MB, SDR and MV designed the study, formulated the research question and elaborated the study protocol. MB and SDR coordinated the implementation of the study. MB, SDR and MV wrote, revised and approved the final manuscript.

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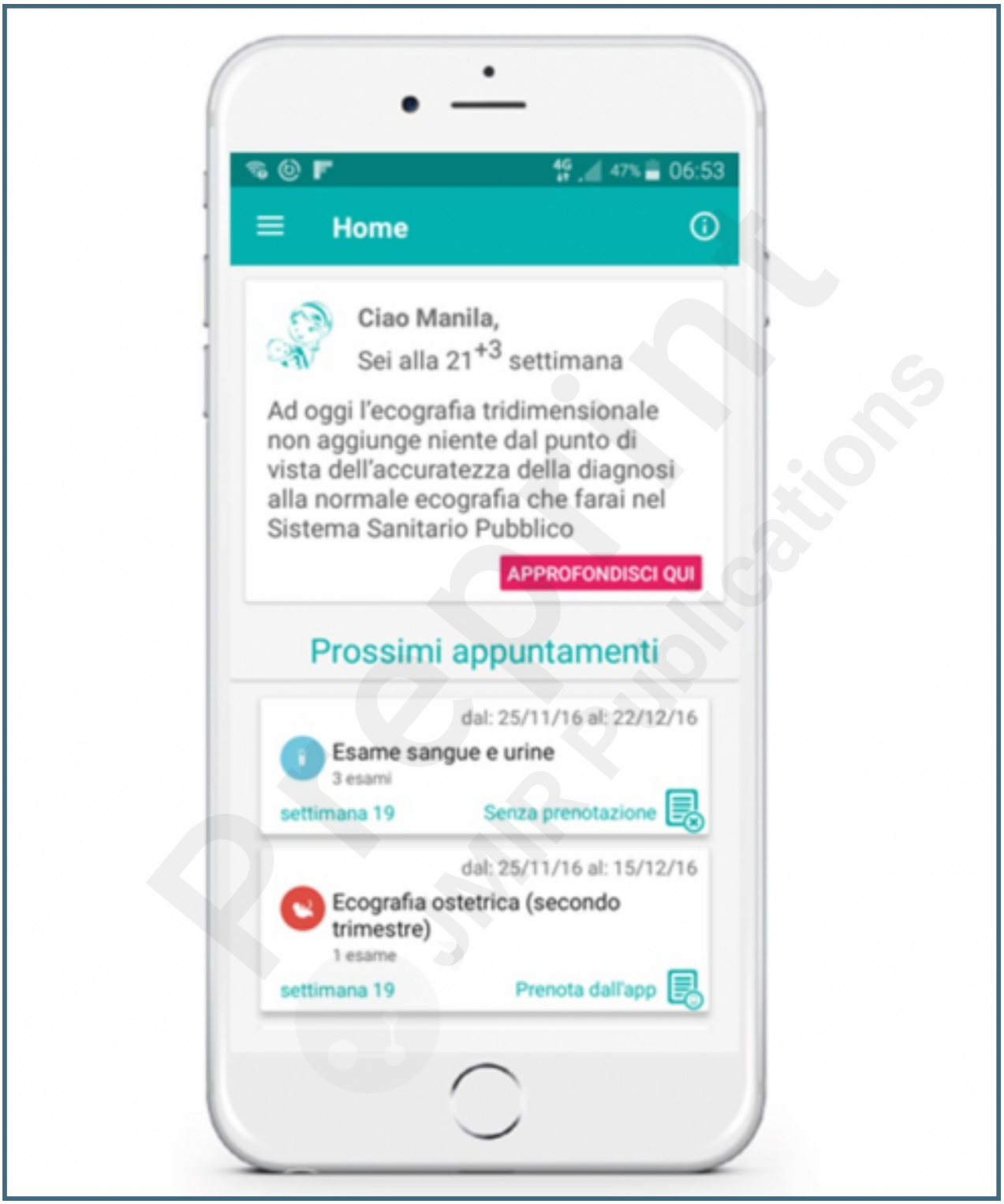
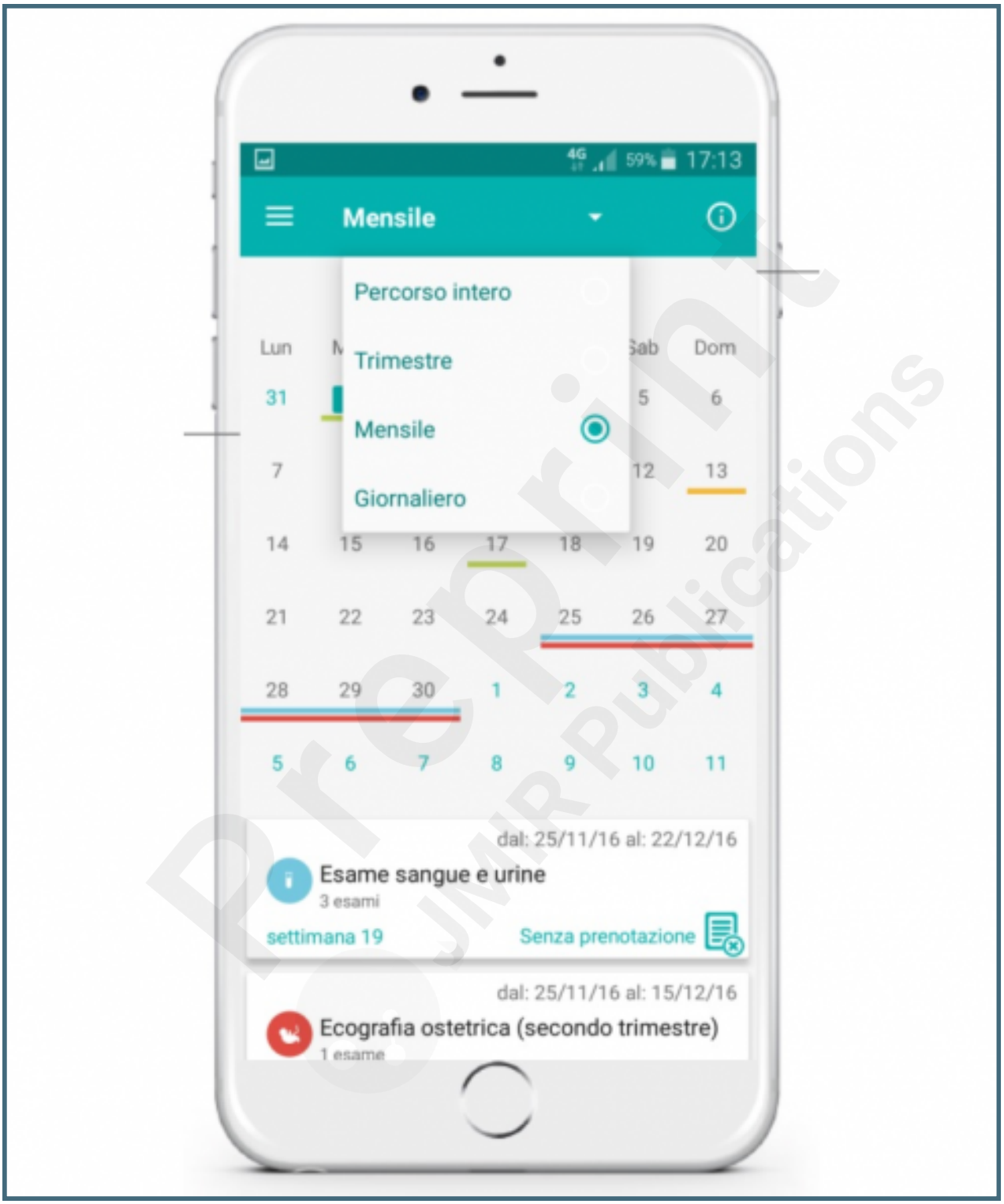
Supplementary Files

Figures

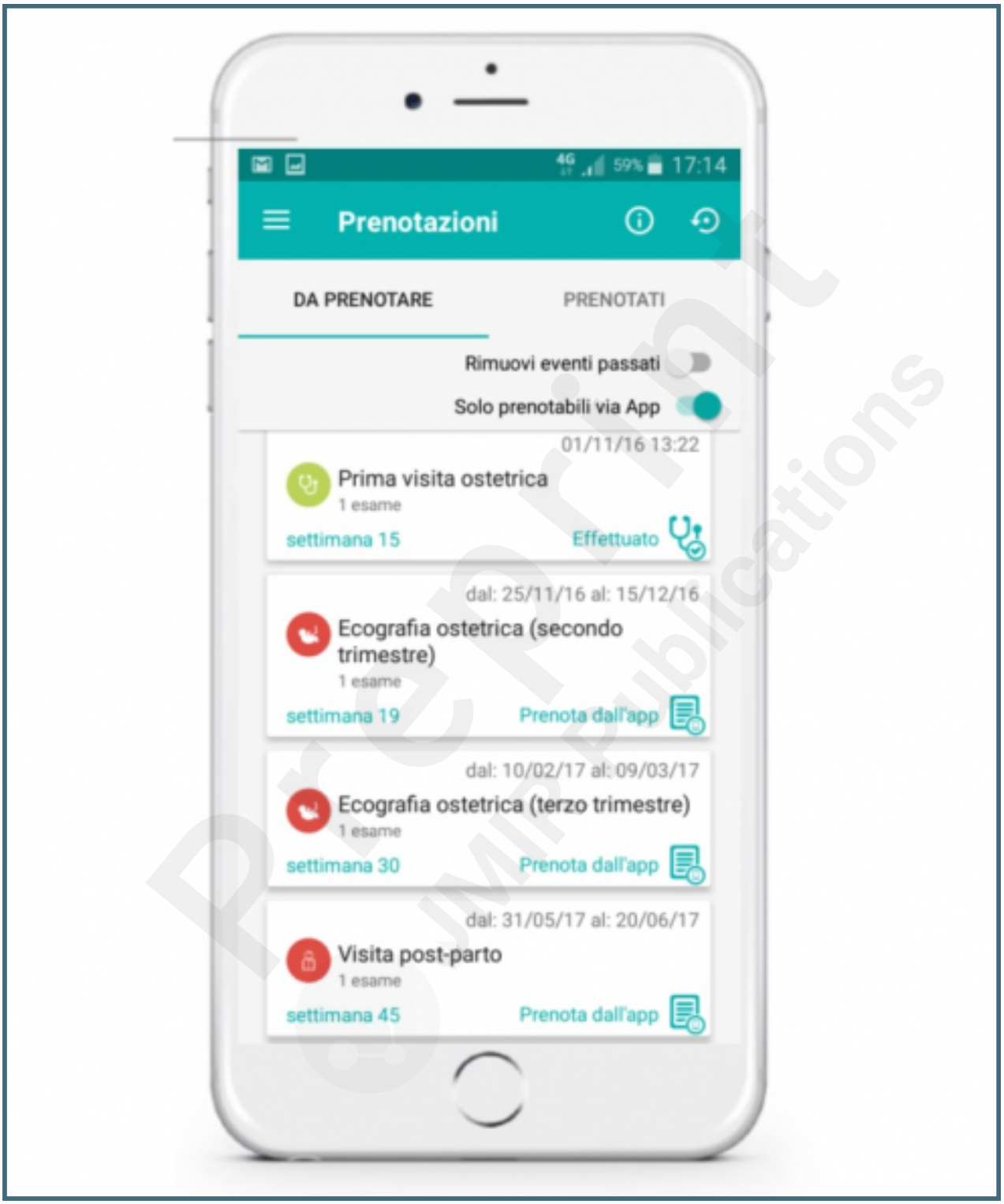
hAPPyMamma homepage: identification of gestational age (during pregnancy) or newborn age (in post-partum); specific messages week-by-week; next appointments memo.



hAPPyMamma agenda: digitalization of pregnancy booklet and infant vaccination calendar into the app agenda with different options of visualization and alert mechanisms.



hAPPyMamma e-booking: visits and tests e-booking via hAPPyMamma; integration into the app agenda and synchronisation with the LHA booking system.



hAPPyMamma information repository: storage of information (in FAQ format) validated by professionals, on health promotion, prevention, healthcare services concerning pregnancy, childbirth and post- partum; information proposed proactively via pop-up messages.

hAPPYMamma facilities repository: storage of information on facilities (family care centers and delivery hospitals), with logistic details, services provided and georeferrring system embedded.