MAP_{APP} : VALIDATION OF A MOBILE APPLICATION FOR PREGNANCY PELVIC FLOOR DYSFUNCTION PREVENTION

Structured Abstract

Aim: To validate the Meu Assoalho Pelvico (MAP) App development as an technology to promote to pelvic floor muscle training and prevent of urogynecological disorders during pregnancy. **Methods:** Validation study of a mHealth technology tool, in Portuguese, for the prevention of pelvic floor dysfunction during pregnancy. The sample consisted of 40 primigravid, between the 16th and 20th gestational weeks. The intervention consisted of a 12-week pelvic floor muscle training exercise program using the MAPapp, with a weekly training frequency of three times in the initial six weeks and four times in the last six weeks. The outcome measures were the questionnaires scores International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Female Sexual Function Index (FSFI). Moreover, at the end of intervention, the level of satisfaction and degree of difficulty with using the MAPapp were questioned. The data were analyzed using the the paired t-test. **Results:** After 12 weeks of use, no differences were found in the ICIQ (p=0,240) and FSFI (p=0,400) scores. As for satisfaction, 85% of the primigravid responded that they were very satisfied, 10% moderately satisfied, 5% equally satisfied and dissatisfied. Only 10% of volunteers reported difficulties with use. **Conclusions:** The MAP App has been validated for use in clinical practice as a technology to promote to pelvic floor muscle training in pregnancy. A randomized clinical trial should be performed to confirm its usefulness for preventing pelvic floor disorders in pregnancy.

Brief summary

The MAPapp was developed by an interdisciplinary team, in Portuguese, consisting of an exercise program based on scientific studies, aimed at pregnant women.

INTRODUCTION

During pregnancy, the urogenital system undergoes several changes that are progressive and caused by biomechanical changes, hormonal actions, increase in weight and size of the pregnant uterus (WOODLEY et al., 2020; MARQUES; SILVA; AMARAL, 2011). The constant overload on the pelvic floor muscle resulting from these transformations can make them ineffective, thus influencing the support and continence mechanism, which increases the risk of developing urogenital dysfunctions during pregnancy and up to 3 months postpartum (WOODLEY et al ., 2017; PALMEZONI et al., 2017). Therefore, it is important to develop measures that maintain the functional conditioning of the pelvic floor muscles for longer, thus avoiding the appearance of pelvic dysfunctions in pregnancy and postpartum (WOODLEY et al., 2020).

The specific pelvic floor muscle training (TMAP) is considered by current studies the gold standard for the treatment and prevention of stress urinary incontinence and sexual dysfunction during pregnancy and postpartum (SANGSAWANG; SANGSAWANG, 2016; BOYLE et al., 2014). This training takes place through the selective contraction and relaxation of the perineal muscles, in order to increase the strength and endurance of such muscles (SANGSAWANG; SANGSAWANG, 2016). Thus, the TMAP helps to maintain the elevated bladder neck (above the pubic symphysis) during increases in intraabdominal pressure, allowing urinary and fecal continence, in addition to supporting the pelvic organs (DUMOULIN et al., 2014).

Despite the effectiveness of TMAP, the positive effects are not maintained in the long term due to low adherence to the exercise program (ELLIOTT et al., 2014). The training is easy, it is not invasive, but it is not attractive for women, which leads to giving up in the maintenance of perineal exercises practice (ELLIOTT et al., 2014). Therefore, physiotherapists and researchers are currently looking for more attractive ways to strengthen the pelvic floor muscles and maintain their performance (ELLIOTT et al., 2014). In this context, mHealth apps can facilitate self-management of the disease,

adherence to treatment, in addition to being able to expand health guidelines for a population with limited access (DANTAS et al., 2021; HAMINE et al., 2015).

Primiparous women who have access to the internet are assiduous consumers of information about maternal and neonatal health, which can influence decisions regarding pregnancy and childbirth, so it is important that the sources of such knowledge are safe and scientifically proven (WALLWIENER et al. ,2016). According to the systematic review carried out by Dantas et al (2020), the applications present in digital distribution services in Brazil present low quality information and do not use authenticated tools to verify the effects of the use of the technology in question. Therefore, the aim of this study was the development of a mobile health application for the prevention of pelvic disorders in primiparae,

METHODS

This was a validation study of a mHealth technology tool for the prevention of pelvic floor dysfunction during pregnancy. This tool was developed by a physical therapist with experience in women's health and a programmer, in order to provide information and a training protocol for the pelvic floor musculature based on scientific evidence for the pregnant public. In addition, this tool was reviewed by information technology professionals and experienced physical therapists working in the area of women's health.

The application in question was named Meu Assoalho Pélvico (MAPapp) and developed in Dart language, flutter framework available only in the Android version. MAPapp contains the following features: training reminder notifications sent by the physiotherapist, visual and sound animation with contraction and relaxation time for proper exercise performance, the history of activities performed each week and the display of the percentage of the program level exercises completed. In addition to providing information about pelvic floor muscles, urinary incontinence and pregnancy. As it is a TMAP protocol, the application does not have the possibility of editing training (number of contractions, rest time and muscle activation), but this information is clarified in

the application. There is the possibility of the user having contact with advanced training in the first access to the technological tool, but it is advisable that the order of the exercises is respected as it is a TMAP protocol.

The TMAP program consists of seven exercises to be performed each day: one pelvic mobilization exercise (anteversion and retroversion or circular movements), three of maximum strength contraction of the pelvic floor muscles sustained for a certain time, one of progression of strength intensity (resistance), a coordination and a metabolite. The program lasts 12 weeks, with a weekly training frequency of three times in the initial six weeks and four times in the last six weeks.The exercises were performed in different positions, with progression of decubitus (dorsal, lateral, sitting on the floor, kneeling, four supports, sitting on a chair, and standing). The amount of contractions and activation maintenance time are increased every 4 weeks, and the pelvic mobilization and metabolite exercises are performed in 2 sets of 10 repetitions. (ELLIOTT et al., 2014). Details of the intervention and progression protocol are described in Chart 1 and Chart 2.

The application was validated through a pilot study with primiparae, between the 16th and 20th gestational weeks, aged over 18 years, who had medical authorization to carry out the physical therapy intervention and who had access to the internet and understanding of its use of the application. Exclusion criteria were: multiple pregnancy, presence of bone deformities, major muscle and nerve dysfunctions, presence of high gestational risk, who has previously performed pelvic floor muscle training, and lower urinary tract infection. This work was approved by the Ethics Committee for Research with Human Beings at the Federal University of Uberlândia under protocol number 4.402.

Volunteers were recruited to participate in the project through advertisements made in telecommunications means, and interested parties were contacted by telephone.

Initially, the pregnant woman was sent a link that forwarded her to the Informed Consent Form and the questionnaires in an online version. The home page consisted of research information and eligibility criteria. All volunteers who agreed to participate in the study ticked the option to confirm accession, with no

limit on the decision time for research participation. Soon after, the participants had access to other pages that contained questions about gynecological and obstetric history, dietary habits, health history and the International Consultation on Incontinence Questionnaire - Short Form (ICIQ), Female Sexual Function Index (FSFI), and Questionnaire International Physical Activity (IPAQ), all validated and translated into Portuguese (HENTSCHEL et al., 2007.; TAMANINI et al., 2004.;MATSUDO et al., 2001).

The ICIQ-SF is a simple, brief and self-administered questionnaire that specifically analyzes how much urinary incontinence (UI) impacts on the quality of life of volunteers, in addition to qualifying participants' urinary loss. This questionnaire has questions that analyze the frequency, severity and importance of UI, in addition to a self-assessment, referring to the reasons or events of UI experienced by patients. (TAMANINI et al., 2004).

Sexual function was evaluated using FSFI questionnaire, which consist of 19 multiple choice questions, ranging from 0 to 5, arranged in six domains: desire, arousal, lubrication, orgasm, satisfaction and pain (dyspareunia) related to sexual function during the last 4 weeks. Possible scores that could be obtained from this questionnaire varied from 2 to 36, and is derivatives by summing the scores on each subscale. The higher the total result, the better the sexual function. The cut-off point for the presence Sexual dysfunction is when the total score less than or equal to 26.5 (NAZAPOUR et al. 2017; FRANCO et al., 2016; HENTSCHEL et al., 2007 LEITE et al., 2007).

The short version of the International Physical Activity Questionnaire (IPAQ), was used in order to characterize the sample according to the level of physical activity level of the volunteers. This contains seven items that estimate the intensity and time spent to perform various physical activities per week, classifying physical activity levels into four categories: sedentary, irregularly active, active and very active (BENEDETTI et al., 2007).

At the end of the 12 weeks, the volunteers were also asked about their level of satisfaction with the use of the application using a graded scale from 0 to 5 in which 0 was not trained, 1= very dissatisfied, 2= moderately dissatisfied, 3= equally satisfied and dissatisfied, 4= moderately satisfied and 5 very

satisfied. On the other hand, the presence of difficulty in using the application was analyzed by means of graded answers in which 1 refers to absence, 2 to medium difficulty and 3 to very difficult. At the end of the questionnaire, the participant could make a criticism or suggestion for improving the application.

Soon after the initial assessment, a video was sent explaining the execution of each exercise and this information was also available in the application.

Training reminder notifications were programmed by the physiotherapist, so there was a pattern of weekly training frequency, but if by chance the pregnant woman could not perform the training on the day the notification was sent, she could use the application at another time, as long as she respected the amount of workouts per week.

Statistical analysis was performed using the Statistical Package for Social Sciences software (SPSS 21, Chicago, IL). Data normality was tested using the Shapiro-Wilk test. To compare the sample characterization data and verify the effects of the intervention, the paired t-test was performed. A two-sided P value of 5% or less ($P < 0.05$) indicated statistical significance.

RESULTS

Forty primiparas participated in the validation process of the MAPapp with an average gestational age of 17 weeks. The characterization of the volunteers can be seen in table 3.

Initially 20% of the participants had urinary incontinence and after 12 weeks of using the MAP app 30% of the primiparous women reported having leaked urine at least once a week through the application of the ICIQ. Despite this increase in percentage, there was no statistically significant difference between the ICIQ scores before and after the intervention through the application ($p=0.240$).

Regarding the data from the FSFI questionnaire, initially 68% (n=27) of the volunteers were sexually active and 13% (n=5) were inactive. During the

intervention 8% (n=3) became active and 13% (n=5) inactive. As for the questionnaire score, no significant differences were observed in the total score (p=0.400), nor in the isolated domains before and after the intervention (TABLE 2). However, there was a trend towards reduction of all questionnaire scores when comparing the values before and after the intervention.

Of the 40 participants, only 4 (10%) declared difficulty in using MAPapp and all participants responded that they would recommend the use of this technology. Regarding the level of satisfaction after 12 weeks with the use of MAPapp, 85% of the pregnant women responded that they were very satisfied, 10% moderately satisfied, 5% equally satisfied and dissatisfied. Regarding the question about what the application facilitated during the performance of the TMAP, 37.5% of the primiparous women answered the description of exercises, 32.5% the stopwatch function, 27.5% the verbal command and 2.5% others.

DISCUSSION

This study proposes a new application for pelvic floor training for the Brazilian pregnant population. After 12 weeks of use, there was no change in the complaints of urinary loss and sexual dysfunction. In addition, a high level of satisfaction was observed among the volunteers and a reduced number of difficulties with MAPapp.

It is known that, with advancing pregnancy, a worsening in the function of the pelvic floor muscles is expected, as well as an increase in the number of incontinent women. According to the cohort of Daly et al (2018), the prevalence of urinary incontinence is higher during pregnancy compared to the pre-pregnancy situation. Palmezoni et al. (2017) concluded that there is a reduction in the strength of the pelvic floor muscles when they compared women in the first and third trimesters of pregnancy due to hormonal issues, changes in the joint and bone system, increase of weight during pregnancy, with such progressive degradation resulting in a greater number of cases of pelvic floor dysfunction in the third gestational trimester when compared to other trimesters and with non-pregnant women. Therefore, it is important that the TMAP is

performed in order not to reduce the strength of these muscles and, consequently, damage their functions (PALMEZONI et al., 2017).

Despite the trend towards an increase in the number of incontinent women with advancing pregnancy, the number of women with complaints found in this study was lower than that described in the literature. Mathias et al (2015) observed that 37% complained of urinary loss in the third gestational trimester. Thus, training with the use of the app may have reduced the number of complaints in the sample of this study, as the importance of TMAP for preventing UI during pregnancy is known (BOYLE et al., 2014). A randomized controlled clinical trial can confirm or refute this hypothesis.

In the present study, the intervention using the cell phone application did not change the sexual function of the users. It is known that the strength of the pelvic floor muscles has a strong positive correlation with the Female Sexual Function Index in pregnant women, thus being a factor to be considered in measures of prevention, treatment and assessment of sexual dysfunctions (SANTOS et al., 2017). The volunteers in this study were initially evaluated in the second trimester and completed the intervention in the last trimester of pregnancy. The non-significance in the reduction of the mean values of the total FSFI score may be due to the fact that it is a natural tendency of the gestational process to decrease this score. This was confirmed in the research by Sacomori et al. (2009) in which pregnant women in the second gestational trimester had a better sexual function than those in the third trimester. This result can also be influenced by the increase in the number of volunteers who became sexually inactive when answering the final evaluation.

The efficacy of TMAP is associated with the ability to correctly contract and relax the pelvic floor muscles, training frequency, adherence to the exercise program, and constant supervision by the physiotherapist (CHEN et al., 2020.; BOYLE et al., 2013). The internal location of the pelvic floor musculature makes it difficult to perceive and visualize the contraction of such muscles (UECHI et al., 2020) a fact that should be taken into account when analyzing the data in the present study, since the volunteers only received verbal instructions for through a video and in each session the application had an explanation of how

the correct contraction should be done, but there was no physical assessment of the contraction capacity and degree of strength. Therefore, some participants may not have correctly activated the pelvic floor musculature during training and thus have not fully benefited from the use of the app for musculoskeletal issues. And despite having registered the execution of the training, there is the possibility that the pregnant woman has tampered with this data.

Although this is a limitation of the present study, it is worth remembering that the use of TMAP apps without prior assessment of the muscles mimics what is found in the daily lives of users, who often start using apps without the recommendation of experts . Even so, it is suggested that new studies be developed to verify the effect of using MAPapp on the musculoskeletal properties of the perineum, to allow the evaluation of its effects on the musculature after the proposed intervention.

It was also observed as a limitation, the presence in the sample of a predominance of participants with complete higher education, which may have facilitated the understanding of the use of technology. Thus, it is necessary to carry out more studies with populations with different levels of education, to verify the usability of this software product.

Mobile health apps can be a cost-effective option for promoting high-quality care, providing information to people who have difficulty in having contact with this type of service, and also being able to improve self-monitoring of health and treatment adherence. (SJÖSTRÖMet al., 2017). But it is important to emphasize that such benefits will be achieved if these products have a development team composed of health professionals, from the information technology area and patients/users (DANTAS et al., 2021), as was the process of elaborating the MAPapp application .

According to the results found with a high level of satisfaction, little difficulty in using MAPapp and the possibility of recommendation, the MAPapp application is a practical tool for implementing TMAP as it can be used anywhere and at any time as long as the user has access to the internet . Therefore, it is an alternative for a greater involvement of the user with her own

health, a new way of preventing pelvic floor muscle disorders and promoting women's health.

After the criticisms made by the participants, the future improvements that will be developed are: the possibility to silence the voice command, the establishment of goals according to the needs of each individual, the possibility to edit the days when reminder notifications will be sent of training, the insertion of the questionnaires used in this study (ICIQ, FSFI) for self-monitoring of the functions of the pelvic floor musculature of future users and the possibility of sharing the performance and training record with other people, for example, for the email address of a health professional.

Conclusion

The MAPapp was developed by an interdisciplinary team, in Portuguese, consisting of an exercise program based on scientific studies, aimed at pregnant women. The MAP App has been validated for use in clinical practice as a technology to promote to pelvic floor muscle training in pregnancy. A randomized clinical trial should be performed to confirm its usefulness for preventing pelvic floor disorders in pregnancy.

Table 1

TMAP	**1-4 weeks**	**5-8 weeks**	**9-12 weeks**
Force –cont. maximum vol.	3 sets of 8 maximal contractions lasting 6 sec between each set. 6 second interval between each repetition.	3 sets of 10 maximal contractions lasting 8 sec between each set. 8 second interval between each repetition.	3 sets of 12 maximal contractions lasting 10 sec between each set. 10 second interval between each repetition.
The Knack	**Blow back of hand (to increase intrabdominal**	**Blow back of hand (to increase intrabdominal**	**Blow back of hand (to increase intrabdominal**

	pressure). 9 cycles of maximum MAP contraction, blowing on the back of the hand, MAP relaxation.	**pressure).** 15 cycles of maximum MAP contraction, blowing on the back of the hand, MAP relaxation.	**pressure).** 21 cycles of maximal MAP contraction, blow back of hand, MAP relaxation.
Resistance ("the podium") **Count submax**	3 “step” of submaximal contraction lasting 6 seconds per level. Sub-maximum 1 - 6" (50%) Sub-maximum 2 -6" (80%) Maximum - 6"	3 “step” of submaximal contraction lasting 8 seconds per level. Submaximum 1 - 8" (50%) Sub-maximum 2 -8" (80%) Maximum - 8"	3 “step” of submaximal contraction lasting 10 seconds per level. Sub-maximum 1 - 10" (50%) Submaximum 2 -10" (80%) Maximum - 10"

Based on Elliot et al (2014)

Table 2. Position of training in relation to intervention weeks

Position	Weeks	Sessions
in supine position	1st; 2nd	1st to 6th
in lateral decubitus	3rd; 4th	7th to 12th
sitting in the	5th; 6th	13th to 16th
kneeling	6th	17th
four supports	6th, 7th	18th and 19th
sitting on the chair	7th, 8th	20th to 23rd
Orthostatic	8th, 9th	24th to 28th,
Switching positions (in a series there are several positions)	9th, 10th, 11th, 12th	29th to 42nd

Table1- Values before and after using MAPapp obtained from FSFI

Variables	Initial Evaluation	Final evaluation	*p-value*
Desire	3.05 ± 1.25	3.00 ± 1.58	0.867
Excitement	3.95 ± 1.54	3.72 ± 1.77	0.557
Lubrication	4.63 ± 1.68	4.10 ± 1.94	0.241
Orgasm	4.25 ± 1.68	4.04 ± 2.10	0.606
Satisfaction	4.46 ± 1.66	4.21 ± 1.82	0.574
Ache	4.97 ± 1.69	4.45 ± 2.09	0.266
total score	25.36 ± 8.64	23.42 ± 10.64	0.400
ICIQ	0.35 ± 0.86	0.67 ± 1.24	

Paired T-test;* $p<0.05$; data are expressed as mean and standard deviation

Table - Characterization of the sample before the intervention

Physical activity level	
Irregularly active (%)	55%
Active (%)	35%
Sedentary (%)	10%
Age (years old)	29.35 (+ 5.49)
Average weight gain (kg/m2)	2.57 (+2.04)
Gestational Weeks	17.87 (+2.38)
marital status	

Married	83%
fondant	13%
Single	5%
Prenatal	
supplementary network	78%
+SUS supplementary network	5%
SUS	18%
daytime urinary frequency	9.4 (+3.82)
nighttime urinary frequency	1.52 (+0.90)
degree of education	
complete higher education	55%
incomplete higher education	18%
Master's degree	8%
Doctorate degree	5%
Postgraduate	10%
Complete high school	4%

Mean + standard deviation