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Article

Research Protocol: HAPPY MAMA alias MAMA DON'T STRESS Project. The effects of an intervention on mindfulness and self-efficacy for the reduction of stress in the new-mothers: a pilot randomized field trial

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Abstract. The present protocol primarily aims at presenting the results of a pilot randomized field trial to assess the effectiveness of an intervention aimed at increasing maternal well-being and self-efficacy, as well as to reduce the stress level of Italian women in the first six months after childbirth. Women with a gestational age and APGAR scores normal will be recruited. The participants will be randomly divided in three groups: collective intervention, individual intervention and control group. The intervention aims to engage and empower new mothers by strengthening their mindfulness in their parenting skills. The duration of the intervention is 3 hours. The first step is characterized by listening and understanding the critical points from the new mother. The second is to analyze the situation considering the sources of discomfort and emotional distress. The operator will evaluate the strategies implemented by the new mother to face problems and difficulties and apply the theory of the self-efficacy. Finally the summary of the topics discussed and analyzed will be done.
Three previously validated questionnaires will be used to monitor the effect of the intervention, namely: the Karitane Parenting Confidence Scale, the Parental Stress Scale, and the Edinburgh Postnatal Depression Scale. Online administration will be used to collect the data. The questionnaire

will be filled in four times, the first before the intervention and the second three times immediately after the intervention, then after three and six months.

Keywords: self-efficacy, mindfulness, stress, post-partum, newborn, mother-Infant, maternal behavior, mother-infant interaction, maternal parenting stress, maternal support

INTRODUCTION

In spite of the popular saying that women have a maternal instinct, the postpartum is a period very commonly accompanied by anxiety, uncertainties, and fear. Women have to adapt to a new routines quickly and are faced with new responsibilities and tasks such as breastfeeding. All can be challenging for a first time mother. The period after birth is often accompanied by changes in sleeping habits, family dynamics, but also changes in the woman's body, and as the presence of several physical health conditions, have been found in the two years postpartum [1–3]. All of that can cause distress and fatigue in a new mother, which can be aggravated in case of lack of social support and sound financial conditions [4].

Until now research on the topic has focused on postpartum depression[5] and postpartum maternal health care is often neglected[6, 7]. Given that the stress and other psychological conditions in this period can have negative consequences for the mother and the baby [8], research in the area of psychological suffering during the period after birth is needed.

When a new mother perceives that the demands she faces exceed available coping resources, she will experience stress [9], and chronic stress can result in mental health problems [10].

It is possible that the transition to motherhood can be eased by health interventions during the postpartum period that give support and information [8, 11]. A pilot study has shown that mothers that received a mindfulness intervention in the perinatal and postpartum period reported significantly higher maternal self-efficacy, mindfulness components, and self-compassion than those in the control group, and also reported lower anxiety, stress, and psychological distress [12]. A qualitative study has revealed that women often feel the need for help after delivery [13]. Evidence from Finland has shown that breastfeeding is eased and continued due to the mother's resources and attitude to breastfeeding, support from the social network and the current appreciation for breastfeeding in society [14], all of which could be increased by a postpartum intervention that gives the support and information to women.

The aim of the current study is to present a protocol for assessing the efficacy of an intervention aimed at increasing the maternal well-being and self-efficacy of Italian women during the first six months after childbirth, in order to prevent postpartum stress and depression.

MATERIAL AND METHODS

Design of the study

The study will be an experimental pilot field trial. The present research will be a multi-centric study to be conducted in three different hospitals in Rome. The CONSORT statement will be followed to perform the research [15, 16].

Eligibility criteria for participants

The following eligibility criteria will be applied:

- Participant must be a woman aged 18 years old or older;
- Participant must be able to communicate in Italian.

They following exclusion criteria will be applied:

- women will be excluded from the study if they or their babies have serious health problems;
- the baby was born at <37 weeks gestation, weighed <2500 g;
- the baby has the APGAR score <7 immediately after birth [17].

Participants will be recruited from the Obstetrics Units of three different Hospitals. Furthermore for organizational reasons, only mothers that live in Rome will be enrolled.

The hospital recruitment of participants will be conducted at 0 to 3 days postpartum by the researchers and research nurses using a brochure explaining the aim of the study.

The recruitment period will in two weeks. Prior to study participation all women who agree to participate will be asked to sign a written consent form and to provide a contact phone number and email.

Ethical approval

Ethics approval for the full study will be obtained from university and hospital's institutional review boards.

Randomization

After taking the consent, the participants will be divided into three groups:

- group that will follow the "**Collective intervention group**," that will be called "G";
- group that will follow the "**Individual intervention group**," that will be called "I";
- control group that will be called "**Control group**" (C).

The allocation of the women in the groups will be randomly. We will create a random number sequence using Epicalc 2000. A researcher will assign the participants to the groups following the number sequence as described below:

- Multiples of three (3,6,9,12, etc.)→ G;
- Multiples of three+1 (1, 4, 7,10, etc.) → I;

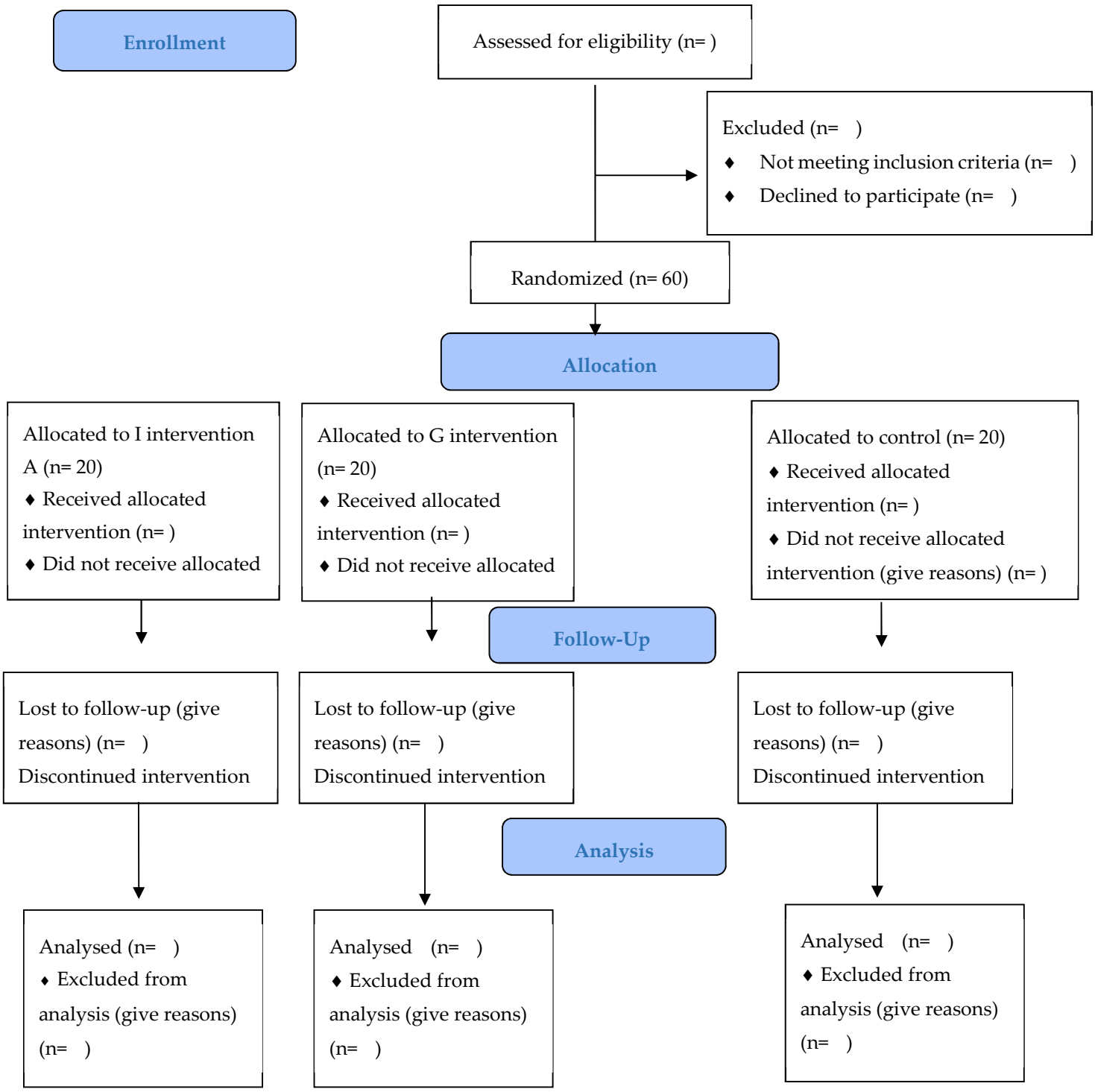
- Multiple of three+2 (2, 5, 8, 11, etc.)→ C.

The groups will be matched for followed variables:

- age (>31 years, 31 is the mean age of Italian women at childbirth (ISTAT, 2017));
- vaginal delivery (Yes/No).

Figure 1 shows the CONSORT diagram of the trial.

Figure 1. CONSORT 2010 flow diagram of the progress through the phases of a parallel randomised trial of three groups



Data collection

The recruitment period will be of two weeks.
During the delivery hospital (T0), we will ask to sign consent forms from each participant and we will collect the demographics information for matching and performing the randomization.
During T0 phase an unique code will be assigned to each women (for example a keyword composed using the first three letter of her name and the last four numbers of her telephone number). A check will be done of the uniqueness, and in case of overlap an adjustment it will be done.
For organizational reasons, one researcher has a paper sheet that reported the codes associated to the women's names.

After the recruitment and the randomization phase, a message that contains the link to the questionnaire will be sent by phone.
The questionnaire is created using a Google form.
The questionnaire will be administered four times (see **Figure 2):**

- At T1: About 30 days weeks after the hospital delivery and 15 days, the last women recruited:
    - For G: the questionnaire will be administered on-line with a phone message with a link to the questionnaire. The message will be sent 2/3 days before the collective intervention. The meeting will be performed about15 days after the last women recruited;
    - For I: the questionnaire will be administered on-line with a phone message with a link to the questionnaire. The message will be sent 2/3 days before the individual intervention. The single intervention will be performed 30 days after the hospital delivery (the 30 days is a hypothesis made considering that in the G group means the time that has elapsed since of giving birth to the intervention is the median range between 2 or 4 weeks).
    - For women in the C group, the questionnaire will be administered online with a phone message with a link to the questionnaire. The message will be sent 30 days after the delivery.
- At T2: About two months after delivery (T2):
    - For G: the questionnaire will be administered online with a phone message with a link to the questionnaire. The message will be sent about one month after the collective intervention;
    - For I: the questionnaire will be administered online with a phone message with a link to the questionnaire. The message will be sent one month after the individual intervention;
    - For C: the questionnaire will be administered online with a phone message with a link to the questionnaire. The message will be sent two months after the delivery.
- At T3: the questionnaire will be administered online with a phone message with a link to the questionnaire. The message will be sent three months after the delivery (T3);
- At T4: the questionnaire will be administered online with a phone message with a link to the questionnaire. The message will be sent six months after the delivery (T4).

Figure 2. Description of the time of follow-up

Questionnaire

The online questionnaire will be used to obtain socio-demographic data, characteristics of breastfeeding practice, mother's confidence about their ability to successfully raise children, and the information on stress and depression.

In order to find the measurements of stress level, self-efficacy and depression in the mothers, a literature search on Pubmed using following search terms "maternal stress, depression, self-efficacy AND (questionnaire or index or inventory)" was conducted on 25th March 2019.

The search display 53 papers, after an analysis of the abstract and the full text we have composed a questionnaire that includes the following three validated scales:

- The **Karitane Parenting Confidence Scale (KPCS)** [18] as a measure of the perceived parental self-efficacy (PPSE), defined as ''beliefs or judgments a parent holds of their capabilities to organize and execute a set of tasks related to parenting a child'' [19]. The 15-item scale, grounded in self-efficacy theory [20], was developed to assess PPSE of parents with infants aged 0-12 months. Factor analysis revealed a three-factor structure, composed of efficacy, support, and child development. An Italian version of the questionnaire will be used.
- The **Parental Stress Scale (PSS**) (21). The PSS scale consisted of 18 items rated on a 5-point Likert scale. The total score was obtained by summing up the value for each item. A higher score indicates a higher level of parental stress. An Italian version of the questionnaire will be used.
- The Italian version of the **Edinburgh Postnatal Depression Scale (EPDS)** [21–23]. For the present study, the EPDS version published by Benvenuti et al. [22] will be considered. This questionnaire is used to measure maternal depressive symptoms. The EPDS is a self-report screening measure to detect symptoms of postpartum depression. Scores >12 on the EPDS are correlated with a diagnosis of major depressive disorder (MDD)[24].

At the baseline, the questionnaire includes additionally a section of demographic variables. The following characteristics will be collected: age, civil status (single or not), employment (student/

worker/ no worker), educational level (middle school/ high school/ university), *the birth date*, primipara (yes/ no), number of children living at home and age, vaginal birth (yes/no), Italian Region where she lives, city where she lives, ethnicity.

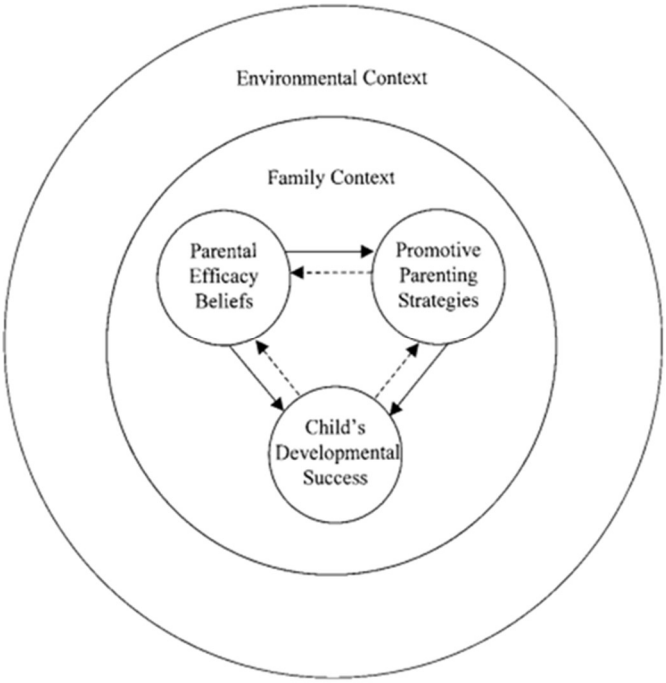
Description of the HAPPY MAMA intervention

<u>Preface</u>

The intervention aims to engage and empower new mothers by strengthening their mindfulness in their parenting skills. High parenting confidence resulting as a key factor in predicting several parent and child outcomes [25] and to acting as a protective factor against maternal depression, stress, relationship difficulties and compromised child development [26]. The conceptual framework underlying the intervention is Bandura's self-efficacy theory that defines self-efficacy as "the belief in one's capabilities to achieve a goal or perform a task and can influence personal motivation and ability to succeed" [20, 27]. This approach was widely used for health promotion and behavioral changes in several contexts and different kinds of patients. In this specific context, parental self-efficacy is defined as "the beliefs or judgments a parent holds of their capabilities to organize and execute a set of tasks related to parenting a child'' [19]. Parental efficacy could also be defined as "the parent's beliefs in his or her ability to influence the child and his or her environment to foster the child's development and success" [28] (**Figure 3**).

Therefore, the HAPPY MAMA intervention is focused globally on the mother-child dyad and aims to provide early parenting strategies that promote both the basic elements for effective child care and behavioral strategies to cope with the changes required in this life development phase.

Figure 3. Conceptual model from Ardelt M & Eccles JS [28]



Personnel involved in the intervention

The operators involved in the administration of the interventions will be health care workers: midwives, nurses, job-infant care worker, and childcare workers, and grad students in Obstetrics that will act as tutors during the interventions.

HAPPY MAMA Intervention at the individual (I) or collective level (G)

The training carried out by a childcare worker and midwives with high experience in childcare and home interventions, includes educational and mindfulness training and simulations of typical events. Given the importance of communication skills training and better outcomes in studies where skills practice has taken place, the interventionists developed their skills through patient simulation and role-play scenarios with one another and the facilitators before interacting with study participants.

1. Objectives

   The objective of the HAPPY MAMA intervention is to explore the effects of early proactive parenting support strategies on mothers' confidence, stress, and mood. The ultimate goal is to share and increase awareness of one's abilities: control and autonomy are important for the final step of the process, the last step wants to put new mothers in a position to implement strategies, and be able to pursue goals to restore mental well-being.

2. Structure

   The phases of the intervention can be educational and support-based, as needed. The educational phase aims to provide information, demonstrations, and discussions while supporting phase aimed at providing social support, counseling, or consultation. The intervention follows several steps:

   (a) Listening and establishing relationship phases

   The first step is characterized by listening and understanding the critical points from the new mother.

   This requires the use of listening skills, empathy, authenticity, and acceptance. The operator maintains a nonjudgmental approach and allows the woman to determine the need for behavioral change, rather than offering unsolicited advice on the need for change.

   (b) Analysis of the problems

   The situation must be carefully evaluated, considering the discomfort and emotional distress. The stress situation will be described in a subjective way, from the new mother, and she will assign a grade of discomfort for each problem.

   (c) Assessment.

   The operator will carry out a multidimensional evaluation of the mother within the dyad. The operator will evaluate the strategies implemented by the new

mother to face problems and difficulties, for example: how she routinely handles organizational problems, how she experiences breastfeeding if there is a lack of sleep and how she considers her family and support network.
The evaluation will have to consider the environment as a whole, with attention to facilitators and barriers.

(d) Definition of the problem and the goal of the intervention
The problems detected by the operator will be explained and summarized to the participants. The operator only explores ways to implement change once the woman expresses the desire and confidence to change.
The shared identification of the mothers' priority will lead to the definition of a tailored plan aimed at achieving specific goals such as the reduction of the stress levels, the decline of the sleep deprivation (hours of sleep per night), optimization of breastfeeding (number, duration and quality), increased well-being (mental health, physical health).
Strategies of concrete action and planned behavior will be provided adapted to the context and styles of women's coping.

Time

Length of the intervention will be 3 hours in one day.

Location

Group interventions will take place at the Department of Public Health and Infectious Diseases of "Sapienza" University of Rome. Individual interventions will be carried out at the women's home.

Sample size

The following parameters were chosen to establish the sample size:

- Average depression score measured with KPDS 2 months after childbirth is equal to mean = 4.63 and SD = 3.23 [29];
- The hypothesis is that the level of KPDS in the GI group will be reduced by 65% (mean=1.62).
- The level of significance and power of the study are respectively 95% and 80%.

On account of these parameters, the sample size is N =18 for each group.
A total of 54 women will be recruited.

We have incremented the sample of 10% for possible missing data and lost to the follow-up.
A total of 60 women will be enrolled: 20 women for each group (I, G, and C).

Statistical analysis

Data will be analyzed using SPSS version25.0 (2018). Descriptive statistics to characterize the sample and analyze the feasibility and acceptability of the study protocol will be used. Measures of central tendency (mean or median) and variability (Standard Deviation, SD, and interquartile range,

IQR) for continuous variables and frequencies and percentages for categorical variables will be calculated.

The outcomes considered in the present study include the scores/index purposed in the questionnaires: PSS, KPCS, and EPDS. We also will describe the outcomes stratifying by demographic characteristics and will monitor in the time (T1, T2, T3, and T4).

A univariate analysis will be conducted to compare the different groups (G, I and C) versus primary (PSS and KPCS) and secondary outcomes (EPDS): ANOVA and Kruskal Wallis's test will be applied to assess the possible difference of scores between the three groups; Chi-square's test will be used to determine possible independence between the three groups versus categorical variables, too.

The tests for paired samples will be used to assess the possible changes of the stress score during the follow-up of the G and me groups (baseline (T1) versus two months (T2), three months (T3) and six months (T4) after the intervention). Moreover, a bivariate analysis will be conducted to assess the possible relationship between the three different outcomes. The correlation coefficient will be computed using Pearson or Spearman's coefficients.

Finally, linear regression models will be used to assess possible significant predictors of the two outcomes PSS, KPCS, and EDPS. Covariates with a $p<0.20$ at the univariate analysis will be included in the linear regression models. R^2 will be computed as the indicator of the goodness of fit of the models. The significant level will be set at $p<0.05$.

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