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Study Protocol

Co-Design and Evaluation of the Feasibility and the Efficacy of a Multiple-Targeted Adapted Physical Activity Intervention to Promote Quality of Life, Well-Being and Physical Activity Levels in Pregnant Women: The "WELL-DONE!" Study Protocol

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Abstract: Background: Regular physical activity (PA) practice during pregnancy offers health and fitness benefits for both mother and baby. Therefore, healthy pregnant women with no contraindications to exercise should be encouraged to perform PA. Nevertheless, their levels of PA are generally low. The aim of the WELL-DONE! Study is to co-design an adapted physical activity intervention (APAI) for pregnant women to include in childbirth preparation classes (CPCs) evaluating its feasibility and efficacy on quality of life (QoL), PA levels and other outcomes. Methods: A quasi-experimental study was divided in two progressive stages. First, APAI was developed in collaboration with pregnant women and midwives using focus groups; second, APAI's efficacy was evaluated comparing two groups: the experimental group engaged in the CPCs integrated with 1 h/week of the APAI administered by midwives and the control group participating in the standard CPCs. Pre-post evaluation was carried out in three stages through questionnaires and tests. Data analysis involved the combination of qualitative and quantitative methodologies. Discussion: Findings from the WELL-DONE! Study will help to assess the feasibility, sustainability, and efficacy of incorporating APAI inside CPCs as a new public health strategy oriented to QoL, well-being, and PA level improvements.

Keywords: pregnancy; childbirth preparation classes; adapted physical activity; exercise intervention; quality of life; co-design; focus group; public health

1. Introduction

Pregnancy is clearly a unique period of life for woman, during which lifestyle behaviors, including the practice of physical activity, can significantly affect their own and their baby's health [1]. Healthy pregnant women with no contraindications to exercise should be thus encouraged to perform physical activity (PA) during pregnancy, since regular exercise practice in such period offers health and fitness benefits for both mother and baby [2,3]. Furthermore, PA has been proposed not only as a preventive measure but also as a therapeutic strategy to reduce pregnancy complications and to optimize maternal–fetal health [4,5], considering that acute physiological responses to exercise are generally increased during pregnancy compared with non-pregnancy [6]. Nowadays, the importance of practicing PA during pregnancy is widely known and recommended thanks also to several guidelines published starting from 2014. Collectively, these guidelines not only outlined the importance of exercise during pregnancy but also provided guidance on

exercise prescription and contraindication for initiating and/or continuing exercise during pregnancy [7–10]. The most recent Canadian guidelines, published with a consensus statement in 2019 and entitled "Canadian guideline for physical activity throughout pregnancy", underline that, in the absence of specific contraindications, regular PA is associated with fewer neonatal complications and increased maternal health benefits such as decreased risk of pre-eclampsia, gestational hypertension, gestational diabetes, cesarean delivery, urinary incontinence, excessive weight gain and depression, improved glycemic control, decreased severity of depressive symptoms, and low back pelvic pain [1]. Moreover, the World Health Organization 2020 Guidelines on Physical Activity and Sedentary Behaviour confirm this evidence and reaffirm the recommendation that all pregnant and post-partum women without contraindications should perform at least 150 min of moderate-intensity aerobic physical activity throughout the week for substantial health benefits [11].

In light of this, exercise practice in the prenatal period should be definitively considered as a first-line non-pharmacological intervention to reduce the risk of complications during pregnancy and to improve the physical and mental health of mothers. In addition, regular PA and exercise, even of low intensity [12], were shown to provide joy and relaxation and to enhance psychological well-being [13].

Nonetheless, fewer than 15% of pregnant women reach the guideline recommendations [1]. Among the possible strategies that allow pregnant women to perform the right dose of PA for health emerges the proactive implementation of adapted physical activity intervention (APAI). APAI is defined as middle-low impact programs specifically tailored to target participants and adapted to their functional capacity, aimed at improving postural alignment, endurance, muscle strength and relaxation, motor coordination, ergonomic education, etc. A recent systematic review on the effectiveness of these interventions demonstrated how this type of intervention is effective in improving the PA levels of pregnant women. Additionally, such exercise programs were proven to be potentially useful not only to relieve pain and psychological symptoms related to pregnancy but also to reduce gestational weight gain and to increase self-efficacy, although firm conclusions cannot be drawn with regard to the latter outcomes and further studies are needed. Furthermore, what is still lacking, according to the review authors, is the effect of these interventions on the quality of life of pregnant women [14]. Admittedly, quality of life (QoL) in pregnancy is an important indicator of woman's health as it investigates her physical, mental, and social well-being. Generally, life satisfaction, happiness, and mental component of QoL are high during pregnancy but other outcomes related to physical components of QoL and positive emotion decreased through the pregnancy, as found by Battaluga et al. in a systematic review of thirty-four studies [15]. Consistent with this, recent studies underline the fact that interventions including quality of life assessment are particularly important as they are potentially able to increase the well-being and quality of care received by pregnant women [16,17]. In this scenario, an ideal setting for the promotion of PA in pregnancy and the implementation of APA programs can be represented by the regular meetings provided by the childbirth preparation classes (CPCs) usually offered by the healthcare system. CPCs are defined as basic courses of preparation for childbirth, conducted by midwives, organized in the family consultants and birth centers settings. In Emilia-Romagna, a Northern Region of Italy, the basic CPCs include from four to six meetings covering several topics such as maternity protection rules, local and hospital services, changes in pregnancy, abilities of the newborn, function of pain during labor and techniques to deal with it, breastfeeding, puerperium, return at home after childbirth, etc. What is still missing among the topics addressed by midwifery inside these CPCs is the presence of PA, above all specifically tailored for pregnant women. Therefore, in order to develop a better clinical practice educational tool, it has been suggested to provide also qualitative studies exploring the needs and the barriers of women not only in achieving recommended amount of PA but also in practicing PA during pregnancy [18]. In connection, there is currently a dearth of co-designed initiatives that aim to refine existing models of preconception and pregnancy care to support women in adopting healthy lifestyles [19]. Furthermore, recent evidence

suggests that bottom-up and co-design approaches with early involvement of healthcare providers and end users able to directly respond to the needs of the target proved essential in developing interventions that are acceptable and sustainable and to guarantee its implementation. For these reasons, these kinds of approaches are recommended [20]. Admittedly, midwiferies are active across both preconception and pregnancy care, and therefore, they have an important role to play in co-designing care that meets the needs and expectations of pregnant women [19]. The main topic of the present work is to outline, using a co-design approach, an adapted physical activity protocol for pregnant women to test and implement in CPCs with the aim to make it safe, feasible, sustainable, and reliable over time.

In this frame, the purpose of the WELL-DONE! Study is to co-design an intervention of adapted physical activity tailored for pregnant women to be included within the childbirth preparation classes and to evaluate its feasibility and efficacy in terms of quality of life, psycho-physical well-being, PA levels, and satisfaction with the proposed intervention. Additionally, health-related fitness, self-efficacy in PA, depression and anxiety states, and finally sleep quality are investigated in order to better assess the effectiveness of the intervention in a holistic view of the mothers and babies'well-being.

The innovative aspects of the WELL-DONE! study concern the progression of two interdependent stages: the co-design of an APAI to be included within CPCs, and its implementation and evaluation. Given the aim of the study, a mixed-method approach is performed to assess pregnant women' and midwives' needs and perspectives in order to potentially enhance the feasibility and sustainability of the intervention [21,22].

Aims of the WELL-DONE! Study in Details

I Primarily, the evaluation of an integrated, co-designed intervention of adapted physical activity, included in the childbirth preparation classes, in order to improve the quality of life of pregnant women.

II Secondly, to assess the feasibility, efficacy, and safety of the intervention in terms of general satisfaction with the proposed intervention, PA levels, health-related fitness, self-efficacy in PA, sleep quality, anxiety, and depression.

2. Materials and Methods

2.1. Study Design

The WELL-DONE! Study is a quasi-experimental study providing two progressive stages according to the aims aforementioned. The first stage (I) regarded the co-design of the intervention through a focus group methodology. Specifically, focus groups with pregnant women who prepared to attend CPCs were conducted with the aim to detect the factors that promote and/or hinder PA in pregnancy; likewise, midwives were invited to participate in separated focus groups for the detection of promoting and/or hindering factors from an operational point of view. In order to develop an adapted physical activity intervention to be administered within the CPCs in a feasible and sustainable way, midwives together with the entire research team in further focus groups aimed to complete the APAI.

The second stage (II) concerns the implementation and the evaluation of the intervention. Thus, the design of the study provides a comparison between two groups: the experimental group, which was engaged in the childbirth preparation classes integrated with the practice for 1 h a week of the APAI program previously designed for this purpose (stage I), while the control group participated in the standard CPCs, at the beginning of which 1 h was dedicated to explaining the recommendation regarding the importance of PA practice during pregnancy.

The WELL-DONE! Study was endorsed by the University of Bologna (Italy). The study administration was designed to allow for effective collaboration and communication between the two departments belonging the University of Bologna. The study was approved by the Ethical Committee Area Vasta Emilia Centro of Emilia-Romagna Region, Italy, on the 11th of November 2020 (Prot. n. 984/2020/Sper/AOUBo of 19 November 2020). This study was

performed in accordance with the ethical standards of the Declaration of Helsinki and its later amendments. The trial was registered in ClinicalTrial.Gov (NCT04735146).

2.2. Participant Recruitment in the Two Stages

The study setting was the University Hospital of Sant'Orsola in Bologna located in Northern Italy. In both stages, participants were recruited on a voluntary basis. As far as the stage I was concerned, invitation letters were sent both to midwives of the Operative Union of Obstetrics of the University Hospital and to pregnant women who prepared to attend the childbirth preparation classes organized by the hospital. Those who wished to participate were contacted via telephone for an interview aimed at delivering the study details and relative informed consent. At the end of the meeting, once the written informed consent was obtained, the focus group could be planned. Since there were no exclusion and inclusion criteria for this stage, pregnant women participating in the focus group were not be eligible for the other stage of the study.

In stage II, pregnant women from the 24th to the 32nd weeks were recruited. Participation in the study was offered to all women interested in the institutional CPCs of the University Hospital of Bologna. Potentially eligible women who express their willingness to participate received an invitation letter to inform them about the study, asking them to contact the research team by telephone in order to attend an obstetric interview aimed at delivering the study information and relative informed consent. After that, women who wish to participate and express their positive written consent were contacted via telephone for an interview, focused on verifying the inclusion and exclusion criteria. Considering the COVID-19 pandemic, women interested in participating in the project recruited before June 2021 were automatically included in the control group. As soon as it was possible to carry out gym group PA, the women interested in the project could join the experimental group.

The WELL-DONE! Study established the following eligibility criteria:

Inclusion Criteria:

- Pregnant women between their 24th and 32nd weeks;
- Pregnant women participating in CPCs organized by the University Hospital of Bologna.

Exclusion Criteria:

Alterations in communication skills and/or sensory functions so severe that make it impossible to understand and/or execute the instructions given by the trainer (dementia, aphasia, blindness, and deafness):

- Premature Rupture of Membranes (PROM);
- Premature labor;
- Unexplained persistent vaginal bleeding;
- Placenta praevia after 28 weeks' gestation;
- Pre-eclampsia;
- Cervical incontinence;
- Intrauterine fetal growth delay or arrest;
- Multiple pregnancy;
- Uncontrolled type I diabetes;
- Uncontrolled hypertension;
- Uncontrolled thyroid disease;
- Other severe cardiovascular, respiratory, or systemic disorders; and
- Any other condition that the operator deems may contraindicate participation in a low to moderate intensity physical activity program.

2.3. Sample Size

The sample size was performed with a power analysis using the SF-12 questionnaire as the primary outcome measure of the study. The study by Arizabaleta et al. found a difference of five points between those who practiced a PA intervention with respect to the control group, regarding the "General Health" component of SF-12 with an effect size of 0.665130 [23]. Considering the same five-point difference, an alpha error of 0.05,

and a power of at least 0.8, the minimum sample size was estimated as 37 women in the experimental group and 37 in the control group, for a total of 74 participants. Considering a dropout of approximately ~10%, the size of each group becomes 40 women, for a total of 80. The power analysis was performed with G * Power 3.1.9.2.

2.4. Intervention

Participants in the experimental group undergo an APAI that was co-designed during phase I of the study. The gym program was carried out in groups (10 subjects maximum to guarantee distancing) in the hospital gym (1 session/week lasting 1 h), especially equipped, administered by the midwives in collaboration with a trainer with a master's degree in Science and Technique of Preventive and Adapted Physical Activity. Each session was divided into different parts according to the specific aim such as warm up at the beginning and stretching and relaxation at the end. The 6-week APAI aims are described in Table 1.

Table 1. The APAI WELL-DONE! Study.

Aims of the Adapted Physical Activity Intervention Program
➢ Improvement of the quality of life
➢ Increasing physical activity PA levels according to recommended guidelines
➢ Improvement of body awareness through an educational component in order to be able to maintain PA autonomously, even after the end of the intervention
➢ Maintenance and improvement of previous functions (for women previously active) and construction of the motor background for sedentary women
➢ Improve breath control, pain management, and motor control with particular attention to the pelvic floor in order to reduce urinary incontinence
➢ Improvement of physical fitness and functional capacity
➢ Improvement of self-efficacy in PA
➢ Improvement of depressive and anxious states
➢ Improvement of sleep quality

Physical Activity: PA.

The midwives could decide together with the women which exercises to perform for each session, trying to use the whole range of available exercises to extend the benefits. Monthly logbooks were used to record the adherence to the APAI program.

2.5. Data Collection and Outcome Measures

During stage I of the WELL-DONE! Study, additional to personal information (e.g., age, education, and previous pregnancies), the following outcomes were evaluated: (1) quality of life, (2) physical activity levels, (3) health-related fitness, (4) anthropometric evaluation, (5) self-efficacy in PA, (6) depression and anxiety, (7) sleep quality, (8) general satisfaction, and finally (9) adherence. As shown in Table 2, all of the measurements were assessed at baseline T0 and then at the end of the intervention, follow-up (T1), and 3-month follow-up after childbirth (T2) to investigate group differences and changes over time. The comparisons between T0, T1, and T2 allow us to determine the eventual short-term and long-term effects of the intervention. Adherence was recorded by midwives using weekly logs and then measured as the percentage of APAI sessions performed on the total number of scheduled APAI sessions. The reasons for interruptions and abandonment were carefully evaluated during the study period. Moreover, all participants were instructed to contact the research team to communicate adverse clinical events or other reasons of non-participation.

The primary outcome is quality of life measured by the 12-Item Short-Form Health Survey (SF-12) questionnaire [24]. Additionally, to the total score, the average for Physical Components Summary and Mental Component Summary measures was obtained according to the algorithm developed by Ware et al. [25]. Validity and reliability of SF-12 had been previously proven for the Italian version of the questionnaire [26].

Table 2. The WELL-DONE! Study stage I: schedule of enrolment, interventions, and assessments.

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-Allocation**		**Close-Out**
TIMEPOINT	**-T0**	**Baseline (T0)**	**6-Weeks Period**	**Follow-Up after Intervention (T1)**	**3 months Follow-Up after Childbirth (T2)**
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
Adapted Physical Activity Program (APAI)			◆———		
ASSESSMENTS:					
Personal information (Age and Education)		X			X
Quality of Life (SF-12)		X		X	X
Physical activity levels (PPAQ)		X		X	X
Health-related fitness		X		X	X
Anthropometric evaluation		X		X	X
Self-efficacy in PA		X		X	X
Depression (PHQ-9) and anxiety (STAI-X 1)		X		X	X
Sleep quality (PSQI)		X		X	X
General satisfaction				X	
Adherence				X	

SF-12: Short Form Survey; PPAQ: Pregnancy Physical Activity Questionnaire; PA: Physical Activity; PHQ-9: Patient Health Questionnaire; STAI X—1: State—trait anxiety inventory; PSQI: Pittsburgh Sleep Quality Index.

Among the secondary outcomes, the PA levels were assessed using the 36 items Pregnancy Physical Activity Questionnaire (PPAQ) [27]. This questionnaire will be translated, adapted in Italian, and later validated by the research team. Health-related fitness was assessed by the following tests: the sit to stand test [28] and the 6 min walking distance (6MWD) combined with a Rating of Perceived Exertion (RPE) Borg scale of 10 [29–31]. Concerning the anthropometric evaluation, self-reported height and weight status were used. A 10-item direct questions scale with structured answers as the Likert scale was designed ad hoc to assess self-efficacy in PA [32]. The subjective perception of general satisfaction related to the CPCs and PA intervention (APAI) was assessed with a structured interview designed ad hoc for the purpose. Depressive and anxious states were investigated through the Patient Health Questionnaire (PHQ-9) and the State—Trait Anxiety Inventory (STAI-X 1), respectively [33,34]. Finally, sleep quality was assessed by Pittsburgh Sleep Quality Index (PSQI) [35].

2.6. Data Analysis

All of the data were recorded electronically by the research team on a secure file storage system and secured by a password. The data were anonymized by assigning a unique identification number to each record and available only for the research team. As far as the quantitative analysis is concerned, the statistical analysis was performed using SPSS, version 22 (Statistical Package for Social Science) (SPSS Inc. Chicago, IL, USA).

The data were presented as the mean and standard deviation for both experimental and control groups and for the T0, T1, and T2. We used the Mann–Whitney test (for non-parametric variables), the Student's *t*-test (for parametric variables), and the Chi-square test (dichotomous ones) to compare the general characteristics between the groups. One-way ANOVA and ANCOVA, adjusted for covariates, were used to analyze differences between the two groups from baseline to follow-up.

The statistically significant results were set with the *p*-value lower than 0.05. The effect size was calculated to examine the magnitude of any mean differences.

The qualitative analysis was structured following the guidelines for the Standards for Reporting Qualitative Research (SRQR) [36]. The semi-structured interviews and focus groups were audio-recorded, transcribed verbatim, and anonymized before being coded. The data were analyzed using a thematic approach [37], and particularly, the framework method [38] was applied to identify both pregnant women and midwives' perceptions and attitudes to PA. In addition, the analysis was guided by the COM-B model framework [39], proposed to understand the psychological constructs related to human behavioral changes.

3. Discussion

The results from the WELL-DONE! study are useful for clarifying and highlighting the effects of incorporating an adapted physical activity program into childbirth preparation classes as a new public health strategy and an innovative model oriented to helping pregnant women reach the recommended levels of PA and to improving their quality of life and well-being. Admittedly, quality of life in pregnancy is influenced by several factors. A recent systematic review by Legadec et al. found that the main factors associated with a better quality of life were a younger age of the mother, being primiparous, the absence of social and economic problems, having family and friends, feeling happiness for being pregnant, being optimistic, and exercise. Conversely, among the main factors associated with a lower quality of life. there were complications before or during pregnancy, obesity, nausea and vomiting, back pain, sleep difficulties, stress, anxiety, and depression, all aspects on which PA has been shown to have a positive effect [17]. Although physical activity interventions during pregnancy have proved to be effective, there are still too few women who reach the recommended amount of PA for their health; moreover, paradoxically, the reported PA decreases significantly from the second to the third trimesters of pregnancy and in the post-partum period. Furthermore, because sedentary behaviors and physical inactivity have a heavy negative impact on pregnant women's and their children's health, it is becoming increasingly necessary to adopt sustainable and feasible interventions promoting PA. In this regard, according to Chan et al., although several studies have been conducted either in local hospitals or in healthcare or medical centers settings, only two studies investigated the effect of physical activity interventions on quality of life, neither using a co-design approach [14]. Among these, only one study found a significant increase in health-related quality of life in the exercise group compared with controls [23]. Therefore, incorporating APAI as an integral component throughout the healthcare setting of the CPCs may potentially help address the barriers in order to increase PA levels and quality of life among pregnant women [14].

We are aware that the present study does not provide a randomized assignment; for this reason, the analyses were conducted considering any eventual confounding factor. However, our study presents remarkable components. The innovative aspect of the WELL-DONE! study precisely concerns the bottom-up co-design of a APAI program based on the needs, barriers, and facilitators to the practice of PA expressed by both women (for example, the lack of knowledge of safe and useful exercises, the lack of accessible facilities, and specific activities) and midwives, who are likewise involved in focus groups in order to identify possible obstacles to the promotion of PA in pregnancy such as the lack of knowledge regarding types and methods of carrying out PA [21,22]. For this reason, the study makes use of mixed qualitative and quantitative methodologies in order to measure the feasibility, effectiveness, and safety of the proposed intervention, based on the needs expressed.

4. Conclusions

This study protocol describes the design, the procedures, and the methods that were used in the WELL-DONE! Study. This study could provide evidence on the efficacy, effectiveness, and sustainability over the time of a co-design adapted physical activity intervention administered by midwives and incorporated in the childbirth preparation

classes to improve several aspects of pregnancy life period from a holistic and a public health point of view.

Author Contributions: S.M., L.D. and D.P. conceived the study. A.M., D.G., R.M., V.B., V.L. and I.C. contributed to the study design. S.M. drafted the manuscript, which was integrated with important intellectual content by all authors. L.D., D.P. and R.M. supervised the study. The final manuscript was read and approved by all the authors. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee of Area Vasta Emilia Centro (984/2020/Sper/AOUBo; 19 November 2020).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: All relevant data from this study will be made available upon study completion.

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Conflicts of Interest: The authors declare no conflict of interest.

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