Rationale and development of the *Vita Nova* project: and app and service to reduce cardiovascular and metabolic risks in pre-menopausal and menopausal women

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ABSTRACT

Background and purpose: Despite the recent increase in research and development of mobile self-care tools, there is still a marked lack of solutions focusing on prevention of the negative health effects of the menopause. Moreover, most of the solutions that do exist are not based on well-founded user models, such as personas, and fail to exploit the potential of persuasive mobile technology, and thus result in a user experience that is neither engaging nor adaptive.

Methods: We describe how we designed personas during the development of a mobile application for menopause self-care. We applied the principles of the Persuasive Systems Design model and the Just-in-Time Adaptive Interventions framework, together with participatory techniques and demographic data analysis.

Results: The *Vita Nova* App prototype has been successfully completed. The usability of this mobile app and service, designed to accompany and coach women regarding the menopause, automatically adapting to their wants and needs in order to induce positive health-related behavioural changes, is currently being verified through a pilot study in a "real-life" scenario of a small group of healthy peri-menopausal and early- and late- postmenopausal women. This preliminary investigation is now in its final stages.

Conclusions: This approach allowed us to come up with reliable representations of our target users and their goals, which in turn enables us to better define and communicate our project's scope and features. Moreover, this approach is not limited to the menopause domain. In the future, it could also be used, to reliably represent users, when designing mobile self-care solutions in other health-related domains or scenarios of female life.

Further investigations in larger study populations of healthy peri- and post-menopausal women will be mandatory in order to assess the real impact of this app

KEYWORDS

Vita Nova App; self-care application; m-Health; e-Health; cardiovascular risk; menopause; prevention; metabolic.

Introduction

The world's population is aging at a historic rate, and this is seen particularly in the most economically developed countries. This demographic shift implies significant changes at both societal and economic level, and has already started to have a negative impact on public healthcare systems. For these reasons, there has emerged a growing interest in healthy aging and personal self-care methods, especially ones based on Information and Communication Technology (ICT). The plethora of available health and fitness smartphone applications (apps), as well as related research initiatives, are a prime example of this phenomenon. However, most of these apps are merely trackers that do not adapt to users' health status and behaviour, and many do not apply best practices on human-computer interaction (HCI); both of these factors result in poor user adherence. These issues are particularly true of the few available apps (among those aimed at women) that focus on the menopause and its effects [1].

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The symptoms of the menopause can be distressing, particularly as they occur at a time of life that sees women playing an important social role within both the home (family) and the workplace. The hormonal changes that begin during the menopausal transition affect many biological systems. For instance, the signs and symptoms of menopause include central nervous system-related disorders, metabolic, weight, cardiovascular and musculoskeletal changes, skin and urogenital atrophy, and sexual dysfunction. The physiological basis of these manifes-

tations is emerging as complex and related not only to oestrogen deprivation, but also other factors. New findings, coming mainly from longitudinal population studies, show that ethnic, geographical and individual factors affect symptom prevalence and severity. Moreover, and of great importance from a clinical practice perspective, the latest research has highlighted that certain menopausal symptoms can be associated with the onset of other disorders, and might therefore serve as predictors of future health risks in postmenopausal women [2].

In the post-menopause, there emerge long-term manifestations of definitive oestrogen deprivation; for example, urogenital atrophy, skin ageing, and osteoporosis might develop during this time. In addition, a shift towards central body fat distribution, and consequent metabolic alterations, might occur as a result of an increased androgen to oestrogen *ratio*, which is also driven by increased insulin resistance [3].

One of the main complaints from women at midlife is increased weight. Indeed, the prevalence of obesity is higher in postmenopausal women than in premenopausal women. Absolute weight gain in women at midlife seems to be fundamentally related to ageing rather than to the menopause itself [4]. In women aged 40–55 years, the average weight gain was reported by one study to be 2.1 kilograms over 3 years [5]. On the other hand, a phenomenon that does seem to be menopause-dependent is redistribution of body fat; this is characterized by accumulation of mostly visceral adiposity at the trunk, leading to an increase in waist circumference and an obvious change in body shape [6]. Visceral adipose tissue poses a greater health risk than subcutaneous fat and, in general, is an independent cause of cardiovascular disease (CVD), primarily due to an increase in insulin resistance, and the consequent risk of developing diabetes mellitus and metabolic syndrome. Furthermore, cross-sectional and longitudinal studies have provided evidence that ovarian failure is causative of visceral fat accumulation during menopause [7-9].

In women, atherosclerosis and the risk of cardiovascular adverse events increase after the menopause; this might be due in part to the production of pro-inflammatory cytokines and adipokines in visceral adipose tissue. Increased deposition of visceral fat in postmenopausal women might be associated with fat accumulation in other visceral tissues, such as the heart [10]. Indeed, it has been reported that late peri-menopausal and postmenopausal women have markedly greater volumes of heart fat compared with premenopausal women independent of age, race, obesity, or other covariates [11]. The markedly reduced exposure to oestrogen during the menopause might have a negative effect on endothelial cell growth and reduce the inhibitory effect of female sex hormones on the growth and proliferation of vascular smooth muscle cells. Moreover, although blood pressure levels seem to be lower, on average, in premenopausal women than in their male counterparts, this advantage is lost around the time of the menopause. At this time, blood pressure levels start to rise in women, reaching levels similar to those of men of the same age group. These negative changes in cardiovascular features increase the risk of adverse cardiovascular events [12,13].

An emerging concept is that some menopausal symptoms might be predictive of future health complications. Indeed, severe vasomotor symptomatology and poor quality of sleep are associated with an increased risk of CVD and postmenopausal depression. Furthermore, depressive symptoms, vasomotor symptoms and sleep disorders might increase susceptibility to developing cognitive dysfunction, while severe hot flushes have been associated with an increased risk of osteoporosis and bone fracture. Finally, as menopause seems to accelerate the ageing process, it is conceivable that, in addition to loss of ovarian function, the manifestation of menopausal symptoms might be in part due to ageing [3].

The large number of studies performed over the past decade in women transitioning through menopause highlights the need to closely monitor health parameters at this stage of life, and promote a healthy lifestyle. Appropriate healthcare and lifestyle changes should start before the menopausal transition, in order to counteract the emergent cardiovascular risk factors and possibly reduce bothersome symptomatology. It is also important for medical practitioners to consider a woman's home and work environment and her ethnicity, as these factors, too, will profoundly affect her experience as she goes through the menopause. Although the management of symptoms through pharmacological or cognitive-behavioural therapy approaches might improve women's quality of life in the short-term, further research is needed in order to develop new strategies to attenuate long-term health risks that are often intensified by the loss of ovarian function.

Midlife is a time of profound personal and social change for women. The perception and interpretation of menopausal symptoms, and therefore their interference with day-to-day life, are influenced by social and cultural beliefs. At international level, ~20% of women perceive menopause as a disease, even without necessarily being fully aware of its symptoms and health implications [14]. Depending on personal and work characteristics, even mild menopausal symptoms can be distressing for some women, and most women with pervasive menopausal symptoms will experience profound difficulty in coping with daily life. The personal experience of menopausal symptoms, particularly bodily changes related to ageing and the awareness of the loss of fertility, may alter self-image. Life events might produce a change of role and/or identity around the time of the menopausal transition. The 'empty nest syndrome', retirement from work, having frail or ill parents, as well as the loss of a parent or partner are all circumstances that frequently occur at midlife. These new circumstances may imply depleted personal and social networks, a feeling of being relegated to a less prestigious status, and an increase in caregiving activities, with an overall decline in quality of life [14,15]. Thus, midlife and the menopausal transition are often perceived as a time of crisis by women and the presence of distressing menopausal symptoms adds to the perception of deteriorating mental and physical wellbeing, which has indirect consequences on health [16]. Nonetheless, many women instead perceive the menopause as a natural phase of life without negative implications [17]. The reasons for this interpersonal variability in the perception of the menopause might be attributable to the relative intensity of symptoms, but it might also depend on how women interpret and manage these symptoms according to their social position and cultural inclination [18,19].

Approximately 30–40% of women report that menopausal symptoms reduce their performance in the workplace, with the most disruptive symptoms being hot flushes, insomnia, a feeling of tiredness and poor concentration [19]. Even women who are not heavily burdened by menopausal symptoms, often pay a price in the form of a perception of reduced social desirability and feelings of shame or embarrassment, sometimes prompted by unwelcome comments from colleagues [20-22]. Targeted strategies aimed at making the menopausal transition and its symptoms recognised socially and accepted in the workplace [18,23,15] — such as promoting self-help reading matter, specific training, flexible working hours or shift changes, reviews of workplace ventilation and temperature — have proven valuable in helping women to share their experiences with peers, and together seek solutions and develop coping strategies.

However, many women do not appreciate the need to improve their health-related behaviour and lifestyle in order to reduce the negative effects of the menopause. Inspired by the increasing prevalence of smartphones across the general population, we think that an adaptive and personalised app that empowers women regarding their menopausal transition would be a fitting solution to this self-care necessity. This is the main rationale behind the ongoing *Vita Nova* project.

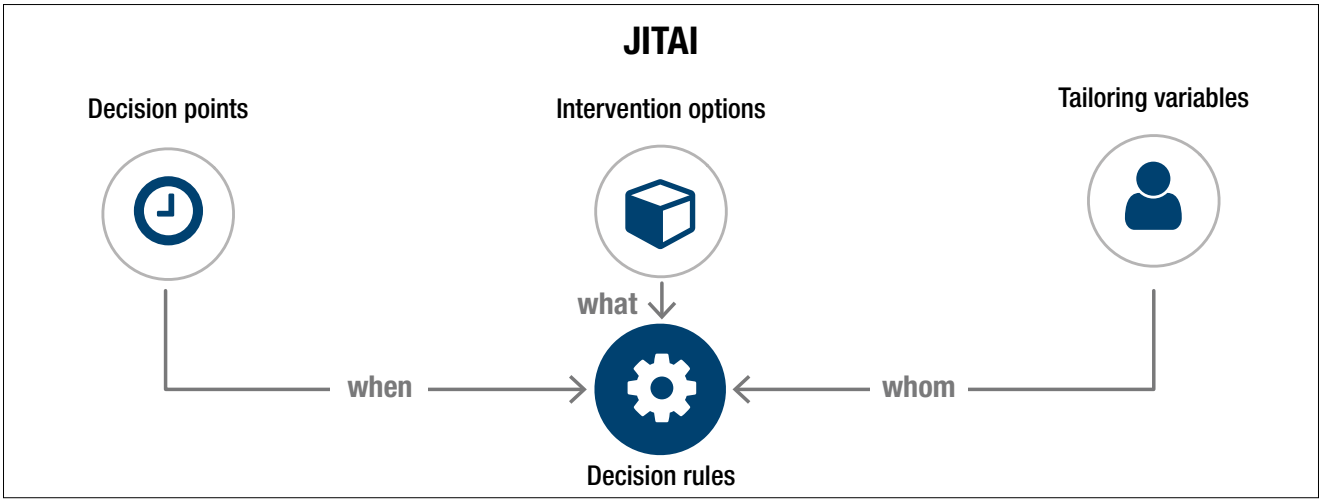
Methods

The *Vita Nova* project consists of the development of a mobile app and service to accompany and coach women regarding their menopause; adaptable to their wants and needs, it is intended to promote health-related behavioural changes. The service's primary goal is to reduce the higher cardiovascular risk caused by the menopausal transition. The project's consortium members are all based in the Italian Region of Tuscany, and have different backgrounds and areas of expertise: three private companies (business and ICT services), a public research organisation (data modelling and HCI research), a public university (experimental gynaecology and socioeconomics research), and an external consultant (psychology). From the very beginning, the consortium decided to utilise a user-centred design, with the intention of increasing user adherence to our health-related app.

The spread of pervasive and ubiquitous computing (e.g. smartphones, wearable devices, domestic sensors) has spurred the development of mobile health technology and solutions for self-care. Nevertheless, available mobile self-care solutions focusing specifically on the menopausal transition are scarce, as is the respective scientific literature. Among the few available apps present in the scientific literature we found MenoPro, developed by the North American Menopause Society. MenoPro helps gynaecology clinicians decide whether their patients should undergo pharmacological treatment for menopause-related symptoms. In addition to the clinician mode, MenoPro also has a patient mode that can be used by women interested in undertaking a treatment, but this mode has very limited features. There is no self-monitoring over time, it is only for women over 45 years old, and behavioural changes are not taken into account [1].

We therefore decided to follow the just-in-time adaptive interventions (JITAI) conceptual framework, which is specific for the design of smartphone solutions that promote health-related behavioural changes based on individual characteristics [24]. JITAI revolves around one or more distal outcomes (targeted behaviours), which in turn are connected to a larger set of short-term proximal outcomes, adapted to the framework's four key components: decision points (when), intervention options (what), tailoring variables (whom), and decision rules (how) (Fig.1). Decision points can be expert-specified or user initiated. The choice of intervention options should be based primarily on the targeted proximal outcomes, as interventions vary in terms of kind of support, source, and delivery mode. Tailoring variables describe the user's health status and behaviour, while decision rules are "if-then" statements, used to decide which intervention options to provide based on the values of a given set of tailoring variables. JITAI has been used successfully in health-related apps for the reduction of depression and anxiety [25], sedentariness [26], and addictive behaviour [27]. In the case of *Vita Nova*, the primary distal goal is to reduce the menopause-related cardiovascular risk, by targeting four specific behaviours: physical activity, diet, alcohol consump-

Figure 1 Main components of the just-in-time adaptive interventions (JITAI) framework.



tion, and smoking. Each of these behaviours has distal goals (e.g., regularly do physical activity, quit smoking) and related proximal goals (e.g. increase number of steps per week, reduce smoking by one cigarette per day).

To this end, our first step consisted of knowledge acquisition and the definition of a representation of women's health status and behaviour. This was done together with experts from the aforementioned consortium members in the bio-clinical, socio-economic, and psychological fields. We also used data from the Italian National Institute for Statistics and Eurostat. Next, and based on the preventive character of *Vita Nova*, we defined our target users as menopausal and pre-menopausal women aged 40–60 years, who were free of chronic diseases, and had a BMI of no less than 18.5 (underweight) and no more than 30 (obesity). We then elicited the main JITAI tailoring variables based on biological, behavioural, and socio-economic determinants, menopause symptoms, and health-related personality traits. Each variable was selected on the basis of its appropriateness for a mobile app, relevance, measurability, and ease of collection. The proposed interventions are mainly textual recommendations and information, as defined by the aforementioned experts.

A set of 75 tailoring variables has already been defined, some of which can be derived from the user's answer to a single question, while others are derived from their answers to two (e.g. BMI) or more (e.g. personality traits) questions. Given the relatively high number of questions, we also specified a subset of mandatory variables: age, BMI, awareness of having hypercholesterolaemia, awareness of having high blood pressure, smoking status, household composition, household dynamics, living with a partner, and leisure time (hours per week). The remaining variables can be gathered progressively, if applicable (e.g. smoking, menstrual cycle). Table 1 lists all the variables and how they are measured/assessed. Notably, considering that the *Vita Nova* App is not being developed as a medical device, none of its sections will contain information about or concern menopausal hormonal therapy or drugs, and these topics will not be raised at any point during the interaction with users.

Results

The prototype of *Vita Nova* App has been successfully completed, and we have already started "real-life" testing of

Table 1 Complete list of clinical, socio-economic and psychological variables for the tailoring of recommendations.

CLINICAL VARIABLES	MEASURE/SCALE	CLINICAL VARIABLES	MEASURE/SCALE
Family history of AMI	yes/no	Consumption of sugary drinks	times/week
Family history of stroke	yes/no	Sweet food consumption	times/week
Family history of hypertension	yes/no	Salt consumption	times/week
Family history of diabetes	yes/no	Consumption of snacks at work	times/week
Family history of colon cancer	yes/no	Ready-made food consumption	times/week
Family history of breast cancer	yes/no	Cured meat consumption	times/week
Family history of osteoporosis	yes/no	Awareness of hypertension	yes/no
Date of birth	date	Awareness of hypercholesterolaemia	yes/no
Weight	kg	Menstrual regularity	yes/no
Height	cm	Heavy menstrual bleeding	yes/no
Menopause onset	age	Hot flushes an inconvenience	Likert 1-5
Menopause onset age	years	Sweats an inconvenience	Likert 1-5
Smoking status	yes/no	Fatigue an inconvenience	Likert 1-5
Smoking	cig-number	Insomnia an inconvenience	Likert 1-5
Beer consumption	ml/week	Vaginal dryness an inconvenience	Likert 1-5
Wine consumption	ml/week	Dyspareunia an inconvenience	Likert 1-5
Hard liquor consumption	ml/week	Genital prolapse an inconvenience	Likert 1-5
Moderate physical activity	min/week	Urinary incontinence an inconvenience	Likert 1-5
Intense physical activity	min/week	Bladder voiding dysfunction an inconvenience	Likert 1-5
Sexual activity	yes/no	Depressed mood an inconvenience	Likert 1-5
Consumption of fruit/vegetables	times/week	Anxiety an inconvenience	Likert 1-5
Consumption of fatty foods	times/week	Irritability an inconvenience	Likert 1-5
Cooking style	type	Mood changes an inconvenience	Likert 1-5
Fish consumption	times/week	Lack of energy an inconvenience	Likert 1-5
Whole meal consumption	times/week	Short-term memory loss an inconvenience	Likert 1-5
Consumption of pulses	times/week	Loss of concentration an inconvenience	Likert 1-5
Sugar consumption	times/week	Musculoskeletal pain an inconvenience	Likert 1-5

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SOCIO-ECONOMIC VARIABLES	MEASURE/SCALE	SOCIO-ECONOMIC VARIABLES	MEASURE/SCALE
Perception of income level	Likert 1-5	Retired since	years
Household composition	number	Perception of retirement	to state
Living with partner	yes/no	Perception of employment	to state
Household dynamics	to state	Caregiving Duty activities	hours
Educational attainment	to state	Cultural activities	yes/not
Perception of leisure time	Likert 1-5	Cultural activities, list	to state
Children	number	Cultural activities, time	hours
Marital status	yes/no	Aesthetic treatments	to state
Employment status	to state	Network of friends	yes/no
PSYCHOLOGICAL VARIABLES	**MEASURE/SCALE**		
Self-efficacy	Likert 0-3		
Self-esteem	Likert 0-3		
Readiness to change	VAS 1-10		

this mobile app and service, designed to accompany and coach women regarding the menopause, automatically adapting to their wants and needs in order to induce positive health-related behavioral changes (Figure 1).

A pilot study on a small group of peri-menopausal, and early and late post-menopausal women is ongoing in order to preliminarily assess the usability and the plausible impact of the prototype on women's quality of life and health.

Discussion

Menopausal symptoms have a substantial effect on women's quality of life and performance in the workplace; increased awareness of these symptoms and acquisition of coping strategies might help to address this issue. While menopause per se is not associated with weight gain, it leads to an increase in total body fat and a redistribution of body fat from the periphery to the trunk, which results in visceral adiposity. In parallel, abdominal obesity and menopausal oestrogen decline are associated with adverse metabolic changes and a higher risk of developing CVDs with a plausible impact on the global socio-economic scenario. From this perspective, the *Vita Nova* project, which consists of developing a mobile app and service designed to accompany and coach women regarding the menopause, automatically adapting to their wants and needs in order to induce positive health-related behavioural changes, could help reduce the higher cardiovascular risk inherently associated with the menopausal transition.

Herein we have presented the principles of persuasive systems and JITAIs, and how we used these to define personas during the interaction design process of a menopause self-care app. This approach allowed us to come up with reliable representations of our target users and their goals, which in turn enables us to better delimit define and communicate our project's scope and features. Moreover, this approach is not limited to the menopause domain. In the future, it could also be proposed in other domains or scenarios of female life such as adolescence or the reproductive period. Following the successful design of the prototype of the app and the forthcoming analysis of the results of the pilot study, further investigations in larger study populations of healthy peri- and post-menopausal women will be mandatory in order to assess its real impact.

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