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# DEARBUMP LTD

## Real-world Validation (Pre-market Report)

Liverpool John Moores University

HEALTH MATTERS
Liverpool City Region

LIVERPOOL JOHN MOORES UNIVERSITY

growth platform
Liverpool City Region Growth Company

INNOVATION AGENCY
Academic Health Science Network
for the North West Coast



Real World Validation (RwV) facilitated by Liverpool John Moores University

in partnership with Dearbump LTD, The Innovation Agency and Liverpool City Region Growth Company LTD.

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# Executive Summary

Literature reveals that although companies often believe that supporting pregnant women and new parents is one of their top priorities, women are often mistreated and experience negative incidences at work, causing women to leave their jobs, or to be forcibly made redundant. For example, around 54,000 women per year leave their jobs due to maternity discrimination in the workplace and around 100,000 per year experience negative workplace interactions including harassing comments about their pregnancies (Equality and Human Rights Commission, 2018). Furthermore, women often hide their pregnancies in the workplace out of fear of not being viewed as a valuable member of the team (Bloomberg, 2015). Consequently, employed pregnant women are 2.8 times more likely to develop postpartum depression (Cho et al., 2022).

In the UK, around 10-15 in 100 women experience postpartum depression (NHS, 2022a). Despite these statistics, there is a lack of good quality mental health care for new and first-time mothers within the NHS. General practitioner and health visitor checks are available for new mothers, but often fail to pick up indications of mental health issues and around half of mothers with postpartum depression go undiagnosed (Royall, 2015; Langdon, 2022). Furthermore, an estimated 1.6 million people are on the official NHS waiting list for mental health support, with around 8 million being unable to get specialist help due to the healthcare system being so overwhelmed. These issues with public health services mean that people are unable to access the immediate care and support they need. Therefore, there is a need for preventative support to reduce the number of people requiring interventions from the already overwhelmed NHS.

Dearbump[1] is a digital platform that supports women throughout various stages of pregnancy and parenthood to reduce symptoms of depression and anxiety regarding work, maternity leave and return to work. Women receive one-to-one support from fully qualified midwives via a chat function that is available 9am – 5pm, 7-days a week.

[1] Dearbump LTD uses an eponymous product name for its digital platform. In this report, all references to the company will use its Companies House registered name of Dearbump LTD. If there is no LTD after Dearbump in the text, then the digital platform is being discussed or referenced.

The innovation value proposition reads as follows – *Dearbump can prevent mental health issues and ease anxieties about working during pregnancy, maternity leave and returning to work.*

A prospective mixed-methods observational study with contrast to a comparison group is proposed, to collect Real World Data (RWD) to evidence the innovation effectiveness and health outcomes. The intervention group data should be compared to the comparison group's data (anxiety levels in pregnant women and first-time mothers with similar sociodemographic characteristics). The primary health outcomes to be considered are user anxiety during three periods: pregnancy, maternity leave and return to work.

The validation protocol should use quantitative measures (e.g., questionnaires such as GAD-7 scale and analysis of user patterns) to gather information on the innovation's outcomes. Qualitative data should also be analysed to assess stakeholders' perceptions, uptake and satisfaction with the innovation (e.g., interviews with midwives and companies).

This report recommends Dearbump LTD to implement the validation protocol to validate the product value proposition. It is recommended that Dearbump LTD use its pre-existing strengths in customer-service oriented provision. Empirical evidence regarding the cost-effectiveness of the Dearbump digital platform can further assist in marketing activities.

## Validation Context

In February 2018, Dearbump LTD company director Emma Jarvis saw a need in the market for assembling products from other manufacturers and selling them as one unit. The product selection for these care package boxes is purposively driven by the goal of having products that match the requirements of mums-to-be at different ante-natal and post-natal stages. For instance, the Trimester 2 Care Package contains products chosen to promote emotional/psychological and physical wellbeing: Calming sleep spray, Lullaby Hand Poured Candle, Mindfulness Cards, Positive wellbeing zine 14 and Spacemask - Self-heating eye mask. There is now a care box tailored to fathers.

In Summer 2021, Ms. Jarvis recognising that parents-to-be need more comprehensive and ongoing support than traditional midwifery services currently offer, particularly in a time of staff shortages, launched a new branch of the company dedicated to an online platform for the delivery of support to parents-to-be from a fully qualified midwifery team. To launch this new service, Ms. Jarvis brought in the biomedical applications and product design expertise of Natalie Parsons and procured the services of a software development team. The resulting WhatsApp-based system is now fully operational. To push the company towards a growth phase, Dearbump LTD has found another company willing to take part in a trial of Dearbump with their staff. Dearbump LTD will use the validation protocol in this report to conduct a validation of their product with NatWest staff.

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## The Challenge

Employers have often stated that supporting pregnant women and those on maternity leave was a top priority of theirs. However, evidence suggests that in the UK around 54,000 working women per year are forcibly made redundant or are treated so poorly that they resigned. Furthermore, as many as 100,000 mothers per year also experience unwanted negative or harassing comments regarding their pregnancy (Equality and Human Rights Commission, 2018). This can put enormous pressure on fathers to become breadwinners, 1 in 3 fathers change jobs when becoming a parent in hope of a better work-life balance and around forty percent of fathers request changes in working hours, but nearly half of these requests are ignored (Deloitte, 2019). The annual economic burden of maternity discrimination in the British workplace amounts to nearly £280 million (Diversity UK, 2016). Furthermore, loss of employees due to maternity discrimination can leave a business at risk of being unable to attract women, forming a bad reputation, presenteeism, gender-imbalanced teams and negatively impacting employee health and wellbeing (Aspire Cambridge, n.d.; Edgley, 2021; Newman et al., 2017; Dorman et al., 2020).

Several countries provide paid leave to assist working parents; however, women frequently continue to work due to financial burdens, negative work environments and fears of losing their job. Consequently, employed women are 2.8 times more likely to develop postpartum depression (Cho et al., 2022). These high figures cost employers up to £4.5 billion a year (Schofield et al., 2011). Approximately 10% of women are affected by postpartum depression within the first year after childbirth (NHS, 2022), a condition categorised by cognitive and somatic changes that interfere with the individual's daily functions. Fathers are also affected, with 1 in 10 being diagnosed with postpartum depression. The condition can have detrimental effects on family life by compromising parental abilities and having negative effects on the child's mental, emotional, and physical development (Garset-Zamani et al., 2020; Ansari et al., 2021). Despite these worrying statistics, there is a lack of good quality care for first-time mothers within the UK from the NHS, with around 50% going undiagnosed and untreated for postpartum depression despite frequent general practitioner and health visitor checks (Royall, 2015; Langdon, 2022). Recently, the World Health Organisation (2022) has made a call for

improvements in screening and psychosocial/psychological interventions throughout pregnancy during antenatal and postnatal periods.

Employee health is paramount to the function of any business. An estimated 1.6 million people are on the official NHS waiting list for mental health support, with around 8 million being unable to get specialist help due to the healthcare system being so overwhelmed (The Guardian, 2021). One report from Deloitte (2020) highlights the mental health crisis in the workplace, with 1 in 6 workers stating that they experience mental health issues and 1 in 4 admit to finding it difficult to mentally switch off from work, leading to mental exhaustion. Moreover, stress is assumed to be responsible for over 50% of working days lost in the UK. Worryingly, only 20% of CEOs believe that their company is able to support employees with mental health problems and only 9% of employees had attended mental health training. Nevertheless, the same report reveals that when employers support their employees, there was a 23% increase in the number of individuals who reported an improvement in their mental health status. On average, every £1 employers spend on supporting mental health creates a return of £5 from their investment, reducing absences, presenteeism and staff turnover, highlighting the benefits that stem from employee mental health support for both the business and workers.

Despite businesses recognising that they need to improve mental health support of their pregnant workforce, they often seem uneducated on how to do so. For example, negative attitudes towards breastfeeding in the workplace often causes hostility, with some women reporting that senior staff members are not accepting or understanding and often suggest bottle-feeding instead, causing women to stop breastfeeding early, being unable to express milk, or being hospitalised with severe mastitis (Chang et al., 2021; Spears et al., 2020). Furthermore, surveys of hundreds of pregnant women revealed that women hide their pregnancies for as long as they can beyond the third trimester by wearing baggy clothing to hide their growing bumps and by masking their morning sickness in hopes of upkeeping their professional image (Bloomberg, 2015). Additionally, 1 in 8 pregnancies end in early miscarriage, many of which occur in the workplace (NHS, 2022b), and many people suffer in silence due to their employers being unaware of the pregnancy (Porschitz and Siler, 2017). Collectively, these statistics are

rooted in lack of communication, which could lead to women switching or leaving jobs unnecessarily.

To tackle these issues, solutions such as pregnancy websites and apps have been created to aid mothers along their journey. For example, in Australia around 75% of new mothers had used at least one pregnancy app to access information on child development, their changing bodies and reassurance. Although, it was identified that midwives and healthcare professionals should have a more central role in these apps to ensure the correct information and support would be given (Lupton & Pedersen, 2016). Moreover, text messaging services between mothers and midwives have proved to be a positive source of motivation and served as a beneficial reminder for appointments and medications (Lau et al., 2014). Similarly, midwives believe these apps are beneficial for women, however, they again point out the risks with misinformation and negative impacts on the patient-midwife relationship (Vickery et al., 2020). Online groups for pregnant women, moderated by midwives, have also demonstrated the effectiveness of remote contact with healthcare professionals, with women stating the groups provided safe spaces to discuss pregnancy/motherhood related topics whilst being provided with reliable and accurate medical advice (McCarthy et al., 2020).

The strains and backlog within public health services indicates that people are unable to access the immediate care and support they need. Therefore, there is a need for preventative support to reduce the number of people requiring interventions from the already overwhelmed NHS. It is evident that the available literature supports the usage of pregnancy apps; however, they must be redefined by placing healthcare professionals at the centre of the design to produce the greatest health outcomes.

## The Innovation

At present, Dearbump offers a personalised service for pregnant women and first-time mothers. 1-2-1 Support is available via WhatsApp where users can receive support from midwives. The midwives will engage in monthly wellbeing checks in which they will be available for questions and advice on birth plans, maternity entitlements, early years of parenting etc. for up to 2-years post-birth. Users can send messages at any time of day, 7-days a week, and will receive replies between 9am and 5pm.

The software is a chat console that has been designed by Dearbump LTD's in-house developer hosted in Salesforce. The console includes a queue of conversations from users and the ability to initiate conversations through pre-approved WhatsApp templates. The console is solely used by the midwives and allows them to manage conversations with various individuals at the same time. Midwives are also able to view the whole chat history of the user, further allowing for personalised responses from the midwives. The software also supports sending bulk messages to batches of users.

The Dearbump digital platform aims to provide support and aid to women throughout various stages of pregnancy and parenthood to reduce symptoms of depression and anxiety regarding work, maternity leave and return to work. The company claims their service is more accessible, convenient and on-demand than their competitors.

Regarding the wellbeing checks, a library of message templates is utilised that are tailored to each stage of pregnancy and parenthood. These messages are designed to be friendly, with a conversational tone. Examples include 20-week scan check-ins, labour prep check-ins, post-birth check-ins and maternity leave check-ins.

Due to WhatsApp business requirements, once 24 hours has elapsed following the last inbound message, a WhatsApp approved template needs to be sent to re-activate the chat. As a result, message design is a large element of the intervention. Once a conversation is active the midwives can take over and respond freely without a prescribed template. The live chat is maintained by a bank of midwives who are fully qualified healthcare professionals. All

midwives are insured to give safe, evidence-based advice and are regulated by the Care Quality Commission.

## Key validation/ research questions

**Value proposition** – *Dearbump can prevent mental health issues and ease anxieties about working during pregnancy, maternity leave and returning to work.*

***Research Question*** *– Is Dearbump a preventative aid for mental health issues, specifically anxiety, in pregnant women and first-time mothers?*

Measured by:

i) Primary health outcomes:
   a. Anxiety outcomes during pregnancy, maternity leave and return to work, measured by quantitative measures

ii) Secondary health measures:
   a. Qualitative measures of stakeholders (midwives and companies)
   b. User patterns of the platform (real-world data)

## Methodology

The ERDF Liverpool City Region (LCR) Health Matters programme developed a working definition of Real-world Validation (RwV) as a methodology that uses real-world data (RWD) to determine, in a non-controlled environment (in the real-world), the effectiveness and the outcomes to patients, staff and the health economy, of a health innovation (Ganga,2021).

Dearbump LTD is on a pre-market stage describing logically, coherently, and convincingly what their innovation offers. As such, the current report assesses the innovation against evidence-based protocols, and against the market competition, Furthermore, the following validation protocol is proposed to allow the SME to collect RWD to evidence the Dearbump digital platform's effectiveness and health outcomes when reaching the market.

## Validation Protocol Design

To validate the Dearbump digital platform, we recommend a prospective mixed-methods study with a comparison group involving the collection of the following data:

- User uptake of the innovation:
    - Analysing user patterns from the platform (evidence of real-world data)
    - How often platform is accessed, how long used during each session, how satisfied users are etc.
- Analysis of user anxiety levels:
    - Assessed at three different stages: pregnancy, maternity leave and return to work
    - Implementing the Generalised Anxiety Disorder-7 Scale (GAD-7) (Spitzer et al., 2006 – https://adaa.org/sites/default/files/GAD-7_Anxiety-updated_0.pdf).
- Stakeholder satisfaction with the innovation:

- Collected through interviews with midwives (who work on the platform) and companies (who have purchased access to the Dearbump digital platform for employees)

A prospective mixed-methods observational study with comparison to a comparison group (MHRA guidance on the use of real-world data in clinical studies to support regulatory decisions - GOV.UK (www.gov.uk)). The intervention group data should be compared to comparison data (anxiety levels in pregnant women and first-time mothers with similar sociodemographic characteristics). The primary health outcomes to be considered are user anxiety during three periods: pregnancy, maternity leave and return to work.

The validation protocol should use quantitative measures (e.g., questionnaires such as GAD-7 scale and analysis of user patterns) to gather information on the innovation's outcomes. Qualitative data should also be analysed to assess stakeholders' perceptions, uptake and satisfaction with the innovation (e.g., interviews with midwives and companies).

## Aims and Objectives

i. To compare levels of anxiety during pregnancy, maternity leave and return to work of those using Dearbump to a comparison group.
ii. To evaluate user uptake data of the platform
iii. To evaluate midwife and company satisfaction with the innovation

## Sample

Recommended sample size per group (i.e., intervention group and comparison group) of 98 and a total sample size (both groups) of 196 (Table 1). Individuals included in the intervention and comparison data should have undergone the same procedure: assessment during pregnancy, maternity leave and return to work.

*Table 1 – Sample size for case-control study*

| | |
|---|---|
| Expected proportion in controls | 0.05 |
| Assumed odds ratio | 4 |
| Confidence level | 0.95 |
| Power | 0.8 |
| Sample size per group | 98 |
| Total sample size (both groups): | 196 |

## Economic Analysis

Depression and anxiety are some of the most common pregnancy related healthcare challenges affecting around 15-20% of women in the first year after childbirth. Mental health issues resulted in 1.27 deaths per 100,000 deliveries in the UK between the years 2006 and 2008 (NICE, 2014). Many of such issues can go unrecognized during both antenatal and post-natal periods. Overall, meta-analyses show significant associations between low social support and the risk of depression, anxiety, and self-harm during and after pregnancy (Bedasco et al, 2021). For instance, a study in the USA showed that continuous labour support even from a layperson led to decreased costs (Greiner, Hersh, Hersh, Gallagher et al., 2019). Professional support may also lead to positive patient outcomes and reduced costs. For instance, a study in Australia reported that a professional doula was potentially cost-saving up to $884 and cost-effective up to $1360 per doula (Greiner, Hersh, Hersh, Remer et al., 2019).

Social support has been severely affected by the Covid crisis thus augmenting some of the challenges described above. Studies suggest the development and use of technology-based programs for greater connectivity, support and advice (Shorey & Chan, 2020). Some of the most common digital interventions to address such issues include screening programs, pharmacological treatments, and various forms of psychosocial and psychological support. The effectiveness of these interventions has been judged using different economic tools and instruments as well as patient outcomes (e.g. smoking cessation, emotional regulation, etc). For instance, for online care, a recent study evaluated the cost effectiveness of a self-guided web-based cognitive behavioural therapy intervention to report a yearly cost-saving of EUR 165.47 and a QALY (Quality-adjusted life-year) gain of 0.0064 (Monteiro et al, 2022). Similarly, a systematic review on mobile health (mHealth )interventions supporting women during pregnancy, reported benefits such as $2168 per DALY (Disability Adjusted Life Years) averted, $203.44 per woman ceasing smoking, and $3475 per QALY gained (Carrandi et al, 2022). Some of these mHealth interventions include mobile phone applications, short message services (SMS) and health monitoring or tracking devices. For instance, a study evaluated the cost-effectiveness of a mobile health-supported lifestyle intervention for pregnant women with an elevated body mass index. It reported a 79% probability that the intervention was cost-effective based on QALYs (O'Sullivan et al., 2020).

The Covid crisis has augmented the role of public health nurses, midwives and doulas in antenatal and post-natal care and support. However, currently, England has a shortage of 2000 midwives (RCM, 2022) and NHS would face a shortage of 40,000 nurses by 2023-24 (Nursing Times, 2022). For private care, a birth doula support package could cost between £800 and £2,000 and a private midwife costs anywhere between £2,000 and £5,000 (Which, 2022). The NHS is facing severe staff shortages and the steep rise in cost of living precludes private maternity care for many patients. As such, DearBump is positioned as a solution where businesses can work to be more responsible by supporting their employees through online and real-time availability of a midwife. For an economic assessment we recommend the following protocol

Baseline demographic data as well as the mental and physical health data at different time points (e.g., early pregnancy, late pregnancy and post childbirth) can be collected, using the

- Whooley questions[2] and the Edinburgh Postnatal Depression Scale in identifying depression and other mental disorders (Howard et al., 2018).
- Quality-adjusted life-year (QALY) profiles.

The primary objective of the economic assessment is to evaluate the incremental cost-effectiveness of usual care only versus the DearBump scenario and to provide an estimate of the incremental net benefit. **For this, the patients will also be asked to fill out the EuroQol-5 Dimensions (EQ-5D) health-related quality-of-life questionnaire. Patients will self-complete an EQ-5D at baseline, which will assess their health-related quality of life. Resulting utility scores may range between 0.0 to 1.0, with 0 representing death and 1.0 representing full health; values below 0 indicate health states worse than death. The standard values for UK will be applied to these responses at each time point to obtain utility scores and QALYs, will be derived from the utility scores. Total costs for the two intervention arms will be estimated by evaluating resources used in usual care and the cost of the intervention.**

[2] The two 'Whooley questions' are: During the past month, have you often been bothered by feeling down, depressed or hopeless? During the last month, have you often been bothered by having little interest or pleasure in doing things? (BJM, 2020).

## Conclusions and Recommendations

This report recommends Dearbump LTD to:

- Implement the validation protocol as soon as possible
- Gather empirical evidence regarding cost-effectiveness for greater impact and lead generation

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