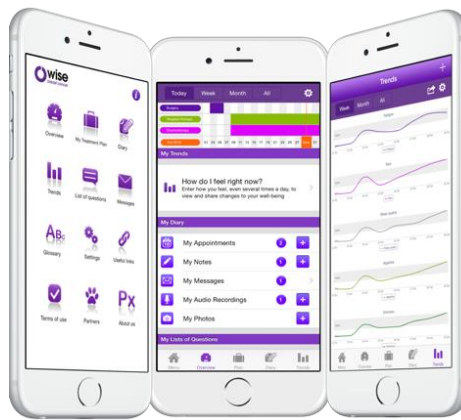# OWise mobile app and website for supporting women with breast cancer

Innovative Medical Technology Overview

Key points

- OWise Breast Cancer is an app and website that offer a suite of tailored information and tools to support women with breast cancer.

- Included in the OWise app is information on disease pathology and care pathways, tailored questions to prompt discussion with healthcare practitioners, an audio-recording function for use in consultations, a symptom tracker and an appointment diary. The ability to share patient symptom data in real-time with the NHSScotland TrakCare® patient record system is being evaluated in NHS Lothian.

- The OWise app is designed for use throughout the patient journey, in conjunction with standard treatments for breast cancer, as a replacement for paper-based support tools.

- There are currently no published studies on the OWise app that report patient health outcomes. There is a local pilot project using the OWise app in NHS Lothian and an ongoing RCT of this tool at the Royal Marsden Hospital (London). No data were available from either project.

- Patients reported positive experiences of using the OWise app.

- Whether the OWise app is cost saving or not is uncertain due to the lack of directly applicable cost and outcome data.

The technology

OWise Breast Cancer is a patient support tool developed by Px HealthCare, which can be accessed as an app on smartphones and tablets, or through a website (http://www.owise.uk/). The OWise app is CE marked as a 'medical device class 1' (low-risk device). The OWise app and website ('OWise app') are synchronised so that patient information is up-to-date, regardless of how or where patients access it.

The OWise app contains a suite of tools to support women with breast cancer[1], including:

1. Personalised information on breast cancer and patient-specific treatment pathways, providing patients with interactive access to extensive information on their condition. All information is sourced from United Kingdom (UK) guidelines and care pathways, supplemented with input from UK-based clinical experts and patient organisations[1].

2. A tailored list of questions to prompt discussions with the oncology care team.

3. A secure audio-recording function, allowing patients to record and replay clinical consultations.

4. Physical and psychological side-effect and symptom tracking. The app records data on 23 symptoms and side-effects, with data on an additional seven included in a beta-version being trialled in NHS Lothian.

5. A diary function that lists upcoming appointments and current stage in the patient's treatment plan.

The beta-version of the OWise app being piloted in NHS Lothian (iOS v1.5.2, Android v1.1.0) has additional functionality that allows integration of real-time patient-reported outcome (PRO) data from the app directly into the TrakCare® (InterSystems Corp.) electronic patient record system. Activation of this feature requires an NHS Lothian-specific code to be entered into the freely downloadable version of the OWise app.

NHS Digital have undertaken a technical review of the OWise app (iOS v1.4, Android v1.0.12, website v1.2) and concluded there were no outstanding technical concerns relating to privacy, confidentiality, security, usability, accessibility, interoperability, technical stability or service/change management[2]. This version of the OWise app did not include the data-sharing function being piloted in NHS Lothian. Px HealthCare state the following security controls are in place for the OWise app:

- Yearly security upgrades and monthly security notifications to users

- Monthly overviews of attempted breaches in security

- 24/7 security, uptime and performance monitoring

- Full compliance with Apple and Google security guidelines, restrictions and policies

- Encryption of all personal data and optional security code to lock the app

- Full compliance with general data protection regulations (GDPR)

- Anonymised and encrypted data storage on European servers by Amazon Web Services.

Innovative aspect

Unlike other PRO-generating apps or systems, the OWise app is freely available to patients and the NHS in Scotland. In the case of the beta-version currently being piloted in NHS Lothian, the OWise app is also uniquely able to feed PRO data directly into the TrakCare® electronic patient record system where it can be accessed by the relevant clinical team.

Patient group

The Owise app is intended to provide support for women who have been diagnosed with breast cancer. The app developer has indicated the OWise app can also be used by people who have survived cancer and patients' partners or family members, for whom there is a special setting.

In Scotland, breast cancer is the most commonly diagnosed cancer in women: in 2017 there were 4,706 new diagnoses[3].

Current practice: comparators and use in pathway of care

The OWise app can be used at multiple points in the patient care pathway to replace, complement, or expand on, current paper-based tools, for example, as a replacement for paper-based chemotherapy diaries for recording side-effects and symptoms during treatment.

The OWise app (without the data-sharing function) is currently used by Barts Health NHS Trust, University College London Hospitals NHS Foundation Trust, NHS Brixton and Sussex, and Manchester University NHS Foundation Trust. In these Trusts and in the pilot project in NHS Lothian, the OWise app is being used mainly as a chemotherapy toxicity management tool in place of paper-based tools. No product performance data were available from these NHS sources.

Other digital apps are available that generate PRO data in oncology, for example the Noona cloud-based mobile service. However, the OWise app is the only one that is freely accessible and, in the case of NHS Lothian, able to integrate with the TrakCare® patient record system.

Product performance: published data

No published data were identified that reported patient health outcomes specifically in relation to use of the OWise app.

Evidence cited by the app developer related to a small number of studies demonstrating the potential patient and clinical benefits of functions supported by the OWise app, such as improved patient-clinician communication, electronic PRO sharing, question prompts for discussion with clinicians, and recording consultations[4-7]. A recent systematic review summarising studies on multiple mobile apps for women with breast cancer, including OWise, concluded that these apps: could be an acceptable source of information to improve patient well-being; could be used to report symptoms or adverse treatment-related effects; and could promote self-care[8]. The review noted a need for further research in the form of randomised controlled trials to examine the effects of the apps on patient health outcomes, as most studies identified in the review focused on assessing functionality and content.

Product performance: local data

As part of the Scottish Cancer Innovation Challenge, a controlled clinical study is being conducted in NHS Lothian using the beta-version of the OWise app. Study participants share PRO data with clinical staff using the integrated version of the OWise app that flags patient health deterioration in the TrakCare® patient record system. Beyond demonstrating the functionality of the Owise app, there are no data from this study to demonstrate the impact on patient treatment or outcomes. Any deterioration in patient health flagged by the OWise app is not currently brought to the immediate attention of clinical staff. In future, wider implementation of the OWise app would require clear policies on who is responsible for monitoring patient records for OWise app PRO alerts, particularly for treatment-related toxicity reports.

Unpublished and ongoing studies

The ADAPT randomised controlled trial (RCT) at the Royal Marsden Hospital in London is comparing outcomes in patients with breast cancer who receive the OWise app plus standard information, with patients who receive standard information alone[9, 10]. The effect of the OWise app on patient activation (a measure of patients' knowledge of their disease and confidence in managing their care), health-related quality of life (HRQoL), health status, psychological distress, NHS resource utilisation and healthcare costs will be assessed. The study is expected to be completed in 2021.

Workshops are planned at several Maggie's Centres in Scotland – a network of drop-in centres to help those affected by cancer – to evaluate user experience with the OWise app among women newly diagnosed with breast cancer.

Safety

No data were identified that reported on safety aspects of the OWise app.

Economic and cost considerations

A case study by the York Health Economics Consortium described potential costs to the NHS of using the OWise app for patients with breast cancer[11]. This study was limited by the lack of directly applicable cost and outcome data. Based on the assumption that PRO data from the OWise app improves symptom reporting, then visits to accident and emergency due to chemotherapy-induced toxicity could be reduced, with an estimated NHS cost saving of £141 per visit avoided.

There are no charges to individual patients or the NHS for use of the OWise app. Annual maintenance costs for the OWise app and website are commercial in confidence and borne by Px HealthCare[11]. The app developer funds future development and maintenance of the OWise app using fees received from subscribers to the OWise PRO Insights data-analytics system. This system is not currently used by NHSScotland.

Information on the cost of integrating the OWise app and NHS IT systems in Lothian is not currently available. These costs will vary between individual hospitals and boards depending on the amount of development and maintenance work required[11]. Px HealthCare will also need to continue investing in the OWise app platform to accommodate changes in IT and software systems over time.

User experience

One published study evaluated patient experience and satisfaction, physician and nurse views, and scientific research potential of the OWise app (v1.0) in consecutive patients newly diagnosed with breast cancer[12]. Patients were asked to use the OWise app for 6 months, following a brief demonstration by a researcher. A single researcher, not involved in patient care, interviewed patients every 2 weeks for 3 months, and then once per month for 3 months. Clinical staff were interviewed shortly after they first saw the OWise app and then approximately 1 month and 3 months later. All interviews were based on a predefined semi-structured guide developed by the study authors. The version of the OWise app evaluated did not have data-sharing capabilities.

Of 40 patients with newly diagnosed breast cancer attending the medical centre during the study period, 19 were invited to participate and 15 agreed[12]. Mean age of patients was 51 years (range 30 to 63). All patients used the audio-recording function in the OWise app and 14 found it useful (one patient felt their recall was sufficient without the recording). Twelve participants used the personalised information; 11 found it useful. Fourteen participants would recommend the Owise app to other patients with breast cancer. Ten clinical staff were recorded at least once by a patient using the OWise app[12]. Two reported choosing their words more carefully when they were being recorded. Nine felt the recordings were useful for patients and nine would recommend the app to patients.

A case study in England noted that the OWise app was used by patients, on average, for three consecutive months (equivalent to the standard treatment period for breast cancer)[13]. During this period the average time spent on the app was 5 minutes per session, and the average time per session on the website was 8 minutes. This case study noted that user experience is monitored by Px HealthCare through workshops, where feedback gathered from patients is used to amend the app[1].

In NHS Lothian, a number of patients have reported receiving amber or red alerts following submission of PRO data. This led to confusion and a lack of confidence in the OWise app among these patients. It is likely this was the result of incomplete screens being saved, causing the OWise app to create an inappropriate alert, or instances where patients felt fine but on further investigation had symptoms that the OWise app had correctly alerted them to. An updated version of the OWise app, released in October 2019, has addressed these issues.

Anecdotally, some patients did not consider completing the OWise app symptom diary a priority when they were feeling ill.

Other considerations

In 2015, the OWise app was selected for roll-out in the UK as part of the NHS Innovation Accelerator programme. The non-data-sharing version is freely available in the NHS England apps library (https://www.nhs.uk/apps-library/).

Implementation of the OWise app in clinical practice will require the investment of time resource to allow staff to become proficient with the app, to give staff time to teach patients how to use the OWise app, and to allow staff to help patients load data onto the OWise app. While this may require additional consultation time, it may alternatively save time by highlighting treatment-related issues as part of teaching patients to use the OWise app. It is

also likely, that with more clinical staff becoming familiar with using smart devices in clinical practice, the time required for these tasks will be reduced.

Conclusions

The evidence base for the OWise app is currently very limited, with no published data on patient health outcomes, safety or cost effectiveness. Evidence from a small study on user experience with the OWise app, and studies suggesting that individual functions within the OWise app could improve patient/clinical outcomes, indicate that this app has the potential to be a useful supportive tool for patients diagnosed with breast cancer.

Recommendations for research

Future research on the OWise app should focus on assessing clinically relevant outcomes, for example, survival, quality of life, patient well-being and NHS resource use, to provide evidence on product performance. Where possible, these studies should contain a comparator group where patients receive an alternative intervention, such as the 'standard information' group in the ADAPT trial mentioned above. This will allow comparisons to be made between the OWise app and current tools, to assess relative performance and costs.

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What is an Innovative Medical Technology Overview (IMTO)

An IMTO is a high-level, light-touch summary of the evidence surrounding an innovative technology. An IMTO seeks to offer an early indication of the strengths and weaknesses of the technology, with a view to contributing to local decision-making by NHS health professionals, managers and procurement colleagues.

IMTOs are not peer reviewed and do not contain recommendations. IMTOs should be considered alongside existing guidance applicable to NHSScotland.

All new and innovative technologies need to have been registered on the NHSScotland Health Innovation Assessment Portal (HIAP).