

# ORCHA Baseline Review Report

OBR v.6.0

The Full ORCHA Baseline Review Assessment Report for:



**APP NAME**  
DrinksRation

**APP VERSION**  
3.0.16

**PLATFORM**  
Android

**DEVELOPER**  
Daniel Leightley

**DATE REVIEWED**  
26/07/2022



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Android

## Overview

We have reviewed your app and found the following results:

### Score Overview

Baseline Review Score:

**82%**

Data Score:

**79%**

Professional Assurance Score:

**80%**

Usability/ Accessibility Score:

**85%**

Level:

**Level 2**

ORCHA ESF Tier:

**Tier 2b**

App Categories:

**Addiction, Alcohol Awareness, Alcohol Monitoring**

### Reviewer Notes

No notes

### Functional Characteristics

During our review, we carry out a functional assessment to generate the functional characteristics. These functional characteristics assist users/ health care professionals in selecting an app which is relevant to them.

The Functional assessment also dynamically changes the lines of enquiry that ORCHA Reviewers follow during the review, again to ensure that the assessment is as tailored as possible to the particular app type. This allows the review to capture an indication of how the app functions and allows all users to tailor their searches appropriately to find apps that actually do the things that they want or need support around.

We have evaluated your app to hold the following characteristics:

☰ Data Capture - The App captures user data.

☰ Data Sharing - The App allows you to share information in the App with others or other Apps/Systems

☰ Goal Setting and Gamification - The App allows you to set health and wellbeing related goals and may support games and challenges around achieving that

☰ Health Monitoring - The App provides functionality to allow users to monitor their conditions, this may involve simple recording of relevant data over time.

☰ Information Provision - The App provides general information.

☰ Service Signposting - The App provides links and suggestions for local or national services that are relevant to its focus area

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## Further App Characteristics

### User Data Collection

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We also examine what user data your app collects. From our review we evaluated your app to collect:

**Sensitive**

### Medical Device

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We also evaluate if an app is likely to be a medical device. We found that your app is:

**Unlikely to be a medical device**

### ORCHA ESF Tier

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We have adapted the NICE Evidence Standards Framework for evaluation within our review. We utilise our functional assessment to generate the ESF Tier and then evaluate against the required evidence for that tier.

**Tier 2b**

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### Designed For

We have also assessed your app against which age group or population it is intended for. The ORCHA designed for categories are:

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#### Everyone

No limit on who can use the app

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#### Adult

18 Years Old +

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#### Child

5-9 Years Old

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#### Teen

13-18 Years Old

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#### Pre-Teen

10-12 Years Old

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#### Infant

0-4 Years Old

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#### Health Care Professional (HCP)

App is Designed for clinician or relevant health care professional

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#### Patient

App can only be used if a patient is linked with a HCP

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#### Research Participant

For people taking part in research or a clinical trial

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#### Career

For the use of a carer

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#### Health Care Administrator

For this use of a health care administrator e.g. scheduling apps

We have assessed your app as being designed for:

**Adult**

Therefore users will be able to filter by this when searching for relevant apps.

# Full Assessment Report

## The ORCHA Baseline Review

At ORCHA we seek out the most popular digital health solutions and review them for compliance and best practice. The majority of solutions we review are Apps (defined as a self-contained software program designed to fulfil a particular purpose, as downloaded by a user to a mobile device). We have extended our scope to also now include Web Apps and Progressive Web Apps (web-based software apps that are customised for a mobile platform, but that are run on a server and accessed via a web browser).

Our ORCHA Baseline Review(OBR) examines how apps comply with relevant regulation and follow best practice. We examine three domains through a set of object questions -Data Privacy, Professional Assurance and Usability/Accessibility. How your app performed in our assessment is shown below.

If you disagree with anyof this information please get in touch at with us at [reviews@orcha.co.uk](mailto:reviews@orcha.co.uk) and we will be happy to discuss our answers and make edits if needed.

## ORCHA Scoring System

The ORCHA score is designed to reward developers for best practice, and highlight poor practice and non-compliance. By following best practice, apps can earn "value points," and poor practice or non-compliance (where necessary) will earn "risk points." The score begins at a baseline of 65% and allows apps to go up or down in score depending on the answers to the questions.

To make the score fair across apps, not every question is asked of every app. For example if the app does not collect any user data, the questions around processing of user data will not be active in the review. We include functional "scene setter" questions at the beginning of the review to capture this.

We also weight the separate sections of the review differently based on the app level. We expect apps with higher levels of clinical functionality, for example one with diagnostic or treatment components to show a higher level of professional assurance than simple relaxation apps. Therefore we weight the section scores across levels.

Level	Data & Privacy	Professional Assurance	Usability & Accessibility
Level 2	30%	40%	30%

Please find a full explanation of our scoring mechanism in the "further information" section at the end of this report.

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## Result Statements

The OBR score, categorisation, functional characteristics and some select review points are displayed to users of our ORCHA app libraries. However, a full breakdown of exactly how we evaluated your app can be found below with the question code and “result statement”. You will be able to see exactly what we have found and given credit for (denoted with a ‘tick’) and advice as to how you could improve your score where we could not find the relevant criteria(denoted with an ‘exclamation point’). For the results to our ‘Scene Setters’ section, we have not included a ‘tick’ or ‘exclamation point’ as these are all none scoring. Once an app has been updated and a new version released, it will automatically be placed in our queue for a “re - review” and will undergo the assessment again.This will capture any changes made by the developer.

A full list of the OBR questions can be found in our Version 6 OBR documentation on our website([www.orchha.co.uk](http://www.orchha.co.uk)).

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## Review Sources

For our review we evaluate the app, the supporting website (if applicable) and the relevant ‘app store’ entry (for native apps).

Our reviewers will also at the time of the review do a general ‘google’ search of the relevant product to check for any related information such as references to Clinical Trials or Studies. These are the review sources(“Review Sources”) and only information that is available publicly through these sources is considered in the review.

Sometimes the evidence we are seeking in the review does exist but has not been made available to end users.We do not believe that this is appropriate for the types of information we assess and will only take into account information that can be freely accessed by end users.

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## Scene Setters

The OBR begins with a series of questions to capture an app's core purpose and functionality. These include the type of data the app collects and the app's primary functions and features. None of our scene setter questions have any scoring implications and are purely to decide on the line of enquiry further in the review.

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### Data Collection Assessment

We evaluate the app and the privacy policy to answer our review questions regarding data collection and usage. The answers to these questions have no scoring implications but alter the line of enquiry for the review. For example, if we did not find that the app collects user data, none of the user data compliance questions will be asked.

#### Question I.D.

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**ORC\_DT10** From our review, we found that the app collects the following user data:

- Age / DOB
- General Identifier eg. NHS No
- Marital Status / Family / Lifestyle / Social Circumstance
- Employment / Career History
- Usage Data
- Race / Ethnic Origin
- Physical and/or Mental Health Data
- Gender (self-declared or observed)

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**ORC\_DT14** Users are required to, or have the option to sign up or register before they can use the app.

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**ORC\_DC01** We found that user data is collected in the following ways:

- other apps
- automatically generated by the app

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### Data Sharing

We evaluate the app and the privacy policy to answer our review questions regarding data sharing.

#### Question I.D.

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**ORC\_DS03** We found that data is, or can be shared/ exported from the app (this excludes cookie data)

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**ORC\_DS09** We found that non-cookie data is shared automatically, as soon as the app is downloaded, based only on agreement to relevant T&Cs or Privacy Policy.

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### Functional Assessment

We examine the app, app store description and associated website (where appropriate) to carry out the functional assessment.

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### Algorithm/AI

#### Question I.D.

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**ORC\_AI01** We found that the app utilises algorithms.

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**Information****Question I.D.**

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**ORC\_I01** We found that the app provides general information or guidance.

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**ORC\_F08** We found that the app provides signposting to local or online services.

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**ORC\_EF07** We found that the app provides information, resources, or activities to the public, patients or clinicians, either about a specific condition or general health and lifestyle.

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**Monitoring****Question I.D.**

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**ORC\_MN02** We found that the app utilises the recording of relevant data over time, for the user to access and review.

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**ORC\_MN03** We found that the app appears to involve automated assessment or interpretation of relevant data, regarding the management of a specific condition.

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**Notifications****Question I.D.**

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**ORC\_D29** We found that the app sends push notifications.

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**Goal Setting****Question I.D.**

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**ORC\_F06** We found that the app provides gamification or goal setting features.

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**Business Model****Question I.D.**

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**ORC\_U29** The app is totally free.

# Level

We have assessed your app to be:

**Level 2**

There are a wide array of different types of health and care Apps available with an equally wide array of functionality and sophistication. ORCHA believe that just because an App offers more complex functionality, it doesn't mean it is automatically better than a functionally simple App. Apps that for example simply provide information and guidance – similar to health 'leaflets' – can be very useful in certain circumstances and this isn't impacted by their relative functional simplicity.

In order to assess and score these Apps in a way that enables a fair comparison of like for like solutions, ORCHA has devised a Level system. These Levels (currently ranging between Level 1 - 4), are indicative of the area of focus an App has (wellbeing, general health or specific conditions) and the level of functional complexity and associated risk. The Levels are an important part of the ORCHA Baseline scoring system which adjusts between each Level to reflect a shifting prioritisation from the usability measures towards the professional assurance review domain (outlined below).

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**Level 1 Well-being / Utility**

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These apps are focused on either general well-being with a health focus or are utility apps used in a health context.

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**Level 2 General Health**

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These Apps are focused on general health.

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**Level 3 Condition Management**

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These Apps can be focused on general health or supporting specific health conditions.

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**Level 4 Regulated**

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These Apps can be focused on general health or specific conditions and contain advanced and complex features that are subject to formal regulation.



## Data & Privacy

Your Data Score:

**79%**

Prior to answering any questions in the Data & Privacy area of the review, the Scene Setters will have captured much of the practical information about the observed data capture and use. There are no scoring implications of the Scene Setter questions. At this point, the review will have determined if any data is collected and retained, which data types are collected and shared, and how that data is used.

The OBR is particularly interested in whether the app collects personally identifiable data, or sensitive data, as well as cookies and device information data. It is to be noted that the OBR does consider cookies and IP address to be personally identifiable data. If the app does make use of cookies, the OBR will consider information also provided within the cookie policy (if available).

Also within the Scene Setters section, the OBR looks at what user data is shared, who it is shared with, how it is shared (either manually or automatically), and whether the user has control or choice over this. The OBR considers whether the app is able to connect to any third party apps, or external devices. If so, it is then considered whether the app offers the user any choice in connecting to other apps or devices. Data sharing to other apps or devices can be of benefit, providing the user has given explicit consent and has control over the sharing of their data.

The OBR looks into data use, data storage and transit, data standards and management and compliance with the General Data Protection Regulation 2018 (GDPR). The review looks into privacy information which is publicly available to the end user, contained within the privacy policy applicable to the health app. The following questions provide detail of what information is expected to be provided to the user in relation to the use of their data.

### Privacy Policy

Initially, the OBR identifies the relevant privacy policy for the app, which is available to users through the app and/or the App Store or Play Store. The more transparent the privacy policy, the better. Ultimately, the privacy policy must clearly state that user data will not be used or shared with other parties, except as described in the privacy policy, or without express consent of the user. Ideally it will identify:

- what data is collected from the user and how
- if the user is informed of the developer's intentions with processing and sharing their data
- if the user's consent is obtained

The privacy policy should accurately reflect the data usage of the app. The reviewers will be able to note if any data is collected outside of what is detailed in the privacy policy. Additionally, the policy should inform users of the developer's intent to use their data for marketing purposes. If user data is shared for any other purposes other than basic use of the app, or legal obligations, then the OBR considers if the user is able to opt out of these activities.

### Privacy Policy Results

ORC_D39a	<input checked="" type="checkbox"/> We identified a privacy policy specifically for the app which is available for users via the App/Web App/Website.
ORC_DP03	<input type="checkbox"/> The privacy policy was not made immediately available to the user upon first opening of the app.
ORC_DP04	<input checked="" type="checkbox"/> We found that the Privacy Policy is made available to the user upon registration.
ORC_DP01	<input checked="" type="checkbox"/> We found that the Privacy Policy is published within the app.

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ORC\_DP05  We found that the Privacy Policy is available via the relevant app store.

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ORC\_DP07  We found some inconsistencies between what is stated to be collected in the Privacy Policy, and the data actually collected in app.

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ORC\_DP14  We found details of a named Data Protection Officer (DPO) within the Privacy Policy.

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#### Data Use

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ORC\_D69  We found that the Privacy Policy fully informs the user of how they will collect user data.

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ORC\_D13  We found that the Privacy Policy provides users with details on all purposes of processing their data.

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ORC\_D38  We found that no user data is intended to be shared or processed for any purpose that has not been made clear to the user.

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ORC\_DP13  We found that the Privacy Policy clearly explains to the user which data processing activities they cannot opt out of, and why.

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ORC\_D16  We found that the Privacy Policy informs the user that their data will not be shared without user consent.

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#### Data Storage and Transit/Transfer

The key areas in this section are surrounding data storage and data transfer. The data privacy policy should inform the user of where their data is stored, how their data is protected in storage, and how it is protected in transit between the user's device and the host storage. The OBR looks for specific and secure storage techniques, such as encryption or firewalls. During transit, it is preferable that data is protected using SSL encryption.

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#### Results

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ORC\_DST01  We found that the Privacy Policy details where data collected by the app is stored.

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ORC\_DST03  We found that the Privacy Policy details that user data is stored using recognised secure data storage technologies.

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ORC\_D17  We found that the Privacy Policy details that user data is encrypted between the device and any external host storage.

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#### Data Standards and Management

If applicable to the app, the OBR will award additional points if an app developer is compliant with any recognised NHS Data Standards such as the Data Security and Protection Toolkit (DSPT), or any International Data Management Standards such as ISO 27001. The privacy policy should inform users of a data retention period, and a method for data destruction. The OBR also identifies whether the developer has a policy in place to deal with any data security breaches.

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#### Results

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ORC\_D19  We found that the Privacy Policy details the length of time which user data is retained.

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ORC\_D20  We found that the Privacy Policy details a method of data destruction for user data, following the expiration of the retention period.

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ORC\_D21  We found the Privacy Policy to detail a process for managing data confidentiality breaches.

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**GDPR**

This review area focuses on the General Data Protection Regulation (GDPR), which in May 2018 came into force to replace the Data Protection Act 1998. The OBR is concerned that all apps, particularly those developed in the UK and the EU, are fully compliant with the GDPR. This means a clear and explicit statement of compliance, as well as confirming that the user is entitled to the 8 user rights, which are:

- the right to access
- the right to rectification
- the right to erasure
- the right to restrict processing
- the right to object to processing
- the right to data portability
- the right to withdraw consent
- the right to request that they are not subject to a decision based solely on automated processing, including profiling

The developer should also inform the user of how they can exercise these rights, and should commit to responding within a time frame of 2 months or less. Under the GDPR, the policy should outline the legal basis for collection of user data, and ensure that only minimal data is collected from the user. All questions relating to GDPR will only be asked for apps that collect and process personal and/or sensitive data.

**Results**

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ORC_D23	<input checked="" type="checkbox"/> We found the app to be compliant with GDPR 2018.
ORC_D60	<input checked="" type="checkbox"/> We found that the user is informed of the legal basis for which data is collected from them.
ORC_DPR03	<input checked="" type="checkbox"/> We found that the developer intends to ensure that data minimisation principles are met.
ORC_D61	<input checked="" type="checkbox"/> We found that should the purpose of data collection change, the user will be informed and consent re-obtained (if consent was the lawful basis).
ORC_DPR01	<input checked="" type="checkbox"/> We found that users are clearly informed of their rights with regards to their data, which they are entitled to expect under GDPR.
ORC_D93	<input checked="" type="checkbox"/> We found that users are clearly informed of their right to request that their personal data is deleted.
ORC_D25	<input checked="" type="checkbox"/> We found that users are clearly informed of their right to access their personal data.
ORC_D56	<input type="checkbox"/> We could not find a statement which clearly informs users of their right to rectify their personal data. This is a user right expected under GDPR
ORC_D81	<input checked="" type="checkbox"/> We found that users are clearly informed of their right to restrict the user of their personal data.
ORC_D57	<input checked="" type="checkbox"/> We found that users are clearly informed of their right to object to the processing of their personal data.
ORC_D59	<input type="checkbox"/> We could not find a statement which clearly informs users of their right to portability of their personal data. This is a user right expected under GDPR.
ORC_D58	<input type="checkbox"/> We could not find a statement which clearly informs users of their right to withdraw consent for the use of their personal data. This is a user right expected under GDPR.

ORC_DPR02	❗ We could not find a statement which clearly informs users of their right to request that they are not subject to a decision based solely on automated processing, including profiling, which produces legal effects concerning him or her or similarly significantly affects him or her.
ORC_D82	✅ We found that users are clearly informed of contact details for the developer, relating to how they can exercise their rights.
ORC_D83	❗ We could not find a statement which clearly informs users of a time frame in which the developer will respond to any requests to exercise their rights, which would ideally be within 2 months.

#### Other Data Questions

This section looks into children's data use (if applicable), and if a user can report knowledge of a child accessing the app without parental consent. The transparency of the privacy policy should extend to inform the user that any links to third party websites or apps are not covered by the developer's privacy policy, and users should make themselves aware of such third party policies. The privacy policy should contain contact details, should the user wish to make further enquiries regarding their data. The OBR also awards additional value points if the app provides the user with an additional, optional layer of security to protect their data.

#### Results

ORC_DO01	✅ We found that users are informed of how they can report any knowledge of a child accessing the app and providing personal data, without parental consent.
ORC_D91	✅ We found that users are made aware that the developer's Privacy Policy no longer applies when following links to any third party websites.
ORC_D92	✅ We found that the user is informed of how they can make further enquiries about the company's Privacy Policy.
ORC_D06	❗ We could not find an option for the user to set their own sharing preferences with or from other connected apps.
ORC_DO03	❗ We could not find any additional, optional security measures for users to protect their data on the app, for example, set additional pass codes for access to the app, after accessing the device is unlocked
ORC_DO04	✅ We found that the app uses a verification/authentication model for the sign up/sign in process.

# Professional Assurance

Your Professional Assurance Score:

**80%**

## Registration Requirements (jurisdiction dependent)

If the app requires registration with a relevant regulatory body, we look for evidence of this. For example, in the UK we examine if the app is registered with the General Pharmaceutical Council(GPhC) and Care Quality Commission(CQC).

## Medical Devices

We first assess if the app is likely to be a medical device under the current guidance from the MDR ([https://ec.europa.eu/growth/sectors/medical-devices\\_en](https://ec.europa.eu/growth/sectors/medical-devices_en)). We then evaluate if the app displays the relevant CE mark.

If a Reviewer identifies that an app is likely to be a medical device under MDR, and the app does not display a CE mark, then the review is assigned to a Senior Reviewer for sign off. If the Senior Reviewer agrees that the app should be displaying a CE mark, the review will not appear on the ORCHA app library. However, the developer will be contacted and we welcome entering a discussion about medical device status.

It should be noted that whilst the V6 assessment has been developed with the forthcoming Medical Devices Regulations in mind, until such time as these Regulations come into force the OBR is calibrated to the existing MDD.

## Results

### ORC\_MD11

❗ Our functional assessment found that the app is unlikely to qualify as a medical device under The Medical Device Directives, and therefore does not need a CE mark.

## Evidence of Effectiveness/Impact

This is examined using the Evidence Standards Framework published by NICE. We conduct an analysis of any evidence available through the Review Resources. If this exists, the app is evaluated against a series of questions to determine the quality of this evidence. We look for:

- a suitable sample size and make up
- a p value of below 0.05 to indicate significance
- a p value below 0.2 for near significance
- an appropriate / validated comparator

This is scaled against the NICE Evidence Standards Framework and we look for a higher level of evidence for apps with more complex functionality and higher risk.

## Results

### ORC\_EE03

☑ We identified the following evidence:

Leightley, D., Rona, R.J., Shearer, J. et al (2020) Evaluating the Efficacy of a Mobile App (Drinks:Ration) and Personalized Text and Push Messaging to Reduce Alcohol Consumption in a Veteran Population: Protocol for a Randomized Controlled Trial. JMIR Publications. <https://www.researchprotocols.org/2020/10/>

ORC_EE04	<input checked="" type="checkbox"/> For the above study, we identified that the sample size was appropriate.
ORC_EE05	<input checked="" type="checkbox"/> For the above study, we identified a p value or confidence interval.
ORC_EE06	<input checked="" type="checkbox"/> For the above study, we identified that the value was significant (p<0.05).
ORC_EE07	<input checked="" type="checkbox"/> For the above study, we identified a comparator.
ORC_EE08	<input type="checkbox"/> For the above study, we could not find that the comparator was validated.

### Professional Backing

We look for evidence of an appropriate professional being involved in the app's design and development, or if the app has been externally accredited. A relevant professional is deduced in the context of an app. For example, for a simple yoga app we would accept a qualified yoga instructor as a relevant professional, but for a complex clinical solution we would only accept a relevantly qualified clinician.

### Results

ORC_PB01	<input checked="" type="checkbox"/> We found that there was a suitably qualified professional involved in the development of the app.
ORC_PB02	<input checked="" type="checkbox"/> We found that the app has been developed by a recognised or national health body.
ORC_PB03	<input type="checkbox"/> We could not find evidence of an endorsement of the app by a relevant body.
ORC_PB04	<input type="checkbox"/> We could not find information showing that there are organisations using the app.
ORC_PB05	<input type="checkbox"/> We could not find information showing that the app has been positively evaluated or validated by a relevant healthcare professional.
ORC_PB06	<input checked="" type="checkbox"/> We found that there is evidence that information within the app has been validated, or has been provided alongside reliable sources or references.

### Safety/Risk Management

The review assesses whether the information in the app will be updated frequently in line with up to date health research, and what that frequency may be. We also look for any safeguarding measures in communication functions of the app, if relevant.

### Results

ORC_S01	<input checked="" type="checkbox"/> We found a clear explanation of who should and who should not use the app.
ORC_S02	<input type="checkbox"/> We could not find the risk management process for the app published for users to see.
ORC_S03	<input type="checkbox"/> We could not find a statement explaining the risks associated with using the app.
ORC_S04	<input type="checkbox"/> We could not find a function which allows the user to confirm that their data input is accurate.

**ESF Compliance**

Your ORCHA ESF Tier:

**Tier 2b**

The first part of this section assesses which ESF Tier the app falls under, and is nonscoring. The second part of this section evaluates the available evidence for the app as described in the Evidence of Effectiveness section. Compliance with the ESF is determined by the app showing the appropriate evidence for its tier.

For further information about the ORCHA adaptation of the NICE ESF, please refer to our website.

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The app was found to have appropriate evidence and **did** meet all the ORCHA ESF criteria for its tier.

# Usability and Accessibility

This section looks at the overall user experience, including usability and accessibility of the app. This includes catering for specific user needs, and providing adequate user support if necessary. To complete this section, our reviewers use all publicly available information. Usually, this consists of any supporting information on the website. Of course, our Reviewers will download and use the app to get a feel for the whole user experience.

Your Usability & Accessibility Score:

## 85%

## Design and Development

The OBR considers the design and development of the app and whether it follows any recognised app design standards, such as WC3, WCAG 2.0 AA, WCAG 2.1 AA, ISO 9241, Apple HIG, or Android App Quality Guidelines. The review also considers whether there was any user involvement during the development of the app, or if any features were based on user feedback.

### Results

ORC_DE01	<span>❗</span> There was no evidence that the app is compliant with any recognised app design standards
ORC_DT01	<span>✅</span> We found a statement that user feedback was collected during design/ development.

## Accessibility

Accessibility is important to consider, as the app should be accessible to all users regardless of their specific needs. The OBR considers whether the app is customisable to suit certain needs, such as poor sight or hearing impairments. If the app uses any specialist or medical terms, these should be clearly explained to the user.

### Results

ORC_U04	<span>✅</span> During our review, the user could change the font size.
ORC_U07	<span>✅</span> During our review, we found that the app did support users with poor sight.
ORC_U08	<span>✅</span> During our review, we found that the app did support users with hearing difficulty.

## Usability

The Usability of the app includes further customisation options. The review identifies if the app has any functions to aid navigation, such as a home, back, help or search features. If the app utilises push or email notifications, the review identifies whether the user has options to manage these for their own preference or privacy. If the app contains a forum, then the OBR looks for a statement to ensure that forum content is moderated. Finally, if there are any bugs identified during review, this will be flagged.

### Results

ORC_U06	<span>✅</span> During our review, we found that the user could change the presentation theme.
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**ORC\_U32**  The app included the following functions:  
- Help/About button

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**ORC\_U15**  We found that specialist terms within the app were explained clearly to the user.

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**ORC\_D31**  We found that the user could control notification settings for convenience/ privacy.

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**ORC\_D32**  We found that the user was informed how to manage notification settings.

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## Support

It is important that users are informed of ways in which they can contact the developer should they have any problems or questions with the app. This is one of the key changes for V6 in the Usability section. The OBR now also asks what type of support is offered to users, and if there is a commitment from the developer to respond to any user queries. We would expect to see the type of support offered is appropriate to the app level - a higher level app would therefore require a more sophisticated offer of user support.

## Results

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**ORC\_U25**  We could not find a statement showing the developer's commitment to addressing user support issues (e.g. timescales to respond, commitment to eradicate reported bugs and faults).

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## User Experience Data

The final section of this review area covers user experience data, and would require clear and specific examples of publication, or sharing of user data.

## Results

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**ORC\_UX01**  We could not find any publicly available unedited User Feedback Data about the app.

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**ORC\_UX02**  We could not find any publicly available unedited User Usage Data about the app.

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## Further Information

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### Review Process and Controls

The OBR is both an assessment framework and an assessment process. The process side of the equation is crucial to ensuring that the overall Review can be undertaken effectively and efficiently. With over 6 years of experience the OBR processes and associated controls have evolved to ensure speed and accuracy can both be achieved.

The OBR is undertaken by one of ORCHA's Professional full time Reviewers who are trained specifically on all aspects of Digital Health assessment and the Standards that underpin this.

The Reviewer undertaking an OBR will download or access the relevant app and explore all of its features. They will then familiarise themselves with the other applicable Review Sources and then commence the assessment.

The OBR assessment is managed through the ORCHA Review Engine which is an online platform that hosts all our ORCHA and Client Reviews. The Review Engine will manage the workflow of the Review and also houses the crucial question and scoring logic that dynamically adjusts the Review in response to the inputs from the Reviewer. This element of the process ensures that the Reviewer answers all required and relevant questions, but is not required to answer irrelevant questions. Upon completion the principle Reviewer will mark the Review as Ready for Sign - Off.

Each Review is signed off by a second Reviewer and for higher Level apps(see above), this sign - off process is always undertaken by a Senior Reviewer. The SignOff process requires the second Reviewer to check specific aspects of the original Review and the scale of these checks is automatically increased the higher the Level of the app.

In addition to the Sign-Off process, spot checks are also undertaken at regular intervals on specific Reviews by the Senior Review Team and the ORCHA Subject Matter Experts. Additionally, the Review team habitually undertake a Calibration Review exercise which entails all Reviewers assessing a specific app and comparing results to ensure all Reviewers are interpreting evidence in the same way.

When a Sign-Off is completed, the relevant Review enters the Publication Process. This involves a 10 Day cooling off period where the Review is only made available to the relevant app Developer. This is done via an email notification which enables the relevant Developer to access a Pre-View of the Review before it goes 'live' on all relevant ORCHA supported Platforms.

Finally, we have a feedback mechanism on all ORCHA supported platforms for end users(professional and none professional) to alert us to any inaccuracies or errors that they believe maybe present in the Review or more broadly any wider concerns or risks they have identified in using the app. We will respond to and look to resolve all such queries within a 7 day period.

We believe that this combination of process controls, checks and feedback loops minimises the risks of inaccuracies in the Review itself.

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## OBR Scoring

The ORCHA Score aims to deliver a meritocratic evaluation with all Apps being treated equally and fairly irrespective of their current popularity or the financial position of their Developers. The primary mechanism is a 'tariff' based model which is described below. This has evolved over many iterations of the OBR and through many interactions with Developers, Health and Care Professionals and the wider expert community.

The aim of the scoring is ultimately reward best practice and highlight poor practice and none compliance. The mechanisms used are designed to ensure that wherever possible the score reflects relative performance and properly differentiates between similar apps.

ORCHA's Line of Compliance is 65%. Any score below 65% would indicate that an App has some issues that users should investigate further prior to using this App. Scores below 45 % indicate that an App has considerable issues or challenges and in its current form is potentially unhelpful or unsafe.

Whilst a high scoring App is not guaranteed to be effective or safe or a poorly scoring App is not necessarily ineffective or unsafe, it does mean that the relevant Developer has taken more or less care over the Apps compliance with these key Standards than other similar Apps. In the critical area of health and care, we believe that developers should take compliance with Standards extremely seriously. No matter how good the user experience of an App might be, if the App is not safe and robust or its treatment of often sensitive health data is not clear and correct, it should be treated with caution.

ORCHA are not promoting or recommending any particular Apps through this process but are providing impartial information about an Apps compliance with standards and a mechanism for end users to easily identify those Apps that best meet those standards and to check which ones don't.

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## Value and Risk Points

The data collected during the OBR – which are detailed in the individual review domain sections below – is either classed as 'scoring' or 'none scoring' data. The scoring elements are used to derive a series of 'section scores' which combine to create an overall ORCHA score. Some scoring questions earn positive ('value') points and some earn negative ('risk') points. Each scoring question has either a Risk implication or a Value implication. The quantum of the Risk or Value implication is decided by the relevant tariff:

- Risk area tariffs range from small, medium, high or exceptionally high.
- Value area tariffs range from small, medium or high.
- In addition to the base Tariff, some Risk and Value related questions attract a ratchet that will increase the relevant Tariff based on certain related app characteristics.

The following table sets out the actual numeric value of each Tariff:

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## For Example:

In the Data Section, the impact of failure to comply with key standards is increased through a Tariff ratchet depending on the nature of the Data captured, i.e. personal data, sensitive data etc. A similar ratchet applies in the Professional Assurance section in relation to an App's compliance with the NICE Evidence Standards Framework. The ratchet here is driven by the ORCHA App Level and increased the Risk Points associated with failure to comply with this framework as the Level of the App increases.

The Tariff based approach is used consistently through all the sections but there are some specific adjustments to the basic model in the Data and Professional and Clinical Assurance sections.

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**Fundamentals**

In addition to the value and risk scoring mechanism, we also utilise “fundamental” requirements in the professional assurance section. If an app does not adhere to a legal requirement (not just best practice or international standard) we give it a professional assurance score of 0, regardless of what the answers are for the rest of the professional assurance section. We also do not showcase any app which has failed “fundamentals” on any of our app libraries. This only comes into effect when an app is required to adhere to these standards (this is determined by the scene setter questions).

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**Section Scoring**

- The baseline score is set at 65% in all sections. This means that if an App does not attract any Risk Points its risk score will equate to 0 which is the equivalent of 65%. If the same App also achieved no Value Points its Value score would be 0 which also equates to 65%.
- If an app attracts Risk Points the total Risk Points will be converted into a % the total possible Risk Points in a given section and this will be the % of the Risk % (65%) that the score will be reduced.
- If an app attracts Value Points the total Value Points will be converted into a % of the total possible Value Points that that app can achieve and this will be the % of the Value % (35%) that the score will be increased by.
- The total Risk accrued is combined with the total Value earned to achieve an overall Section Score.

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**For Example:**

If the total possible Risk Points in a section is 100 and an app accrues 50 of these, it will attract 50% of the risk i.e. 50% of the 65% equivalent to 32.5% If the total possible Value Points in a section is 100 but the app in question could only ever achieve 80 of these points (due to its characteristics) then this is the total achievable Value Points. If the app actually achieves 40 of these then it will earn 50% of the available Value i.e. 50% of 35% equivalent to 17.25% Combining the Risk and Value we end up with a Section Score of  $32.5\% + 17.25\% = 49.75\%$

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**Note:**

It is worth noting the distinction between the approach to calculating Risk which is always based on the total available Risk in that section being the numerator and the actual Risk being the denominator. In the Value calculation however the numerator is not automatically the total available Value in a section but the total Value that any given app could achieve.

The rationale for this distinction is that in the Risk arena, all the available Risks are theoretically possible for all apps and apps either mitigate or eliminate these risks by design or by relevant compliance action. In the Value arena there are many Value elements that an app simply could not achieve because of the nature of the app and therefore it is right that only the Value Points that are achievable should be factored in.

## Get in Touch

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