OBR Report OBR - v6.0.0

The Assessment Report for:



APP NAMEDrinksRation

APP VERSION 3.0.19

PLATFORM Android

DEVELOPERDaniel Leightley

REVIEW COMMENCEMENT DATE

07/12/2022





PLATFORM

Android

REVIEW TYPE

OBR - v6.0.0

Overview

We have reviewed your app and found the following results:

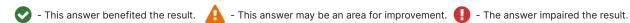
| | Email: | |
|-------------------------|-------------------------------------|----------------------------|
| OBR - v6.0.0 | Version 6.0 of the ORCHA Baseline R | eview |
| Addiction | | |
| Alcohol Monitoring | Alcoh | nol Awareness |
| App Categories: | | |
| Passed | Passed | |
| Professional Assurance: | Reviewer Comments: | |
| Passed | Passed | Passed |
| Scene Setters: | Data: | Usability & Accessibility: |
| Section Fundamentals | | |
| Professional Assurance: | | |
| | | |
| 82% | 79% | 85% |
| | | Usability & Accessibility: |

www.orchahealth.com

Scene Setters

Fundamentals:

Passed









| Question Code | Question and Answer | Impact |
|---------------|--|------------|
| ORC_SS01 | Is the app health focused? Yes | 6 |
| ORC_D01 | Does the app collect data? Yes | 1 |
| ORC_DT10 | What type of data is collected by the app? Name (Full Name, Nickname or First Name Only), Email, 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) | 1 |
| ORC_DT14 | Are users required to sign up / register to use the service? Yes | 1 |
| ORC_DT13 | Is the Data (cookie and/or none cookie) Collected: Sensitive | (1) |
| ORC_DC01 | How is none cookie data collected? manual user input, other apps, automatically generated by the app | (1) |
| DRC_DC02 | What other apps is the App connected to? Google Fit | 6 |
| ORC_DS03 | Can/is data shared? (excluding cookies) Yes | 6 |
| ORC_DS04 | Can data be shared through a direct, manual action by the user? {e.g. by sending data via email or manually choosing to post/share something within the app etc} No | 6 |

| ORC_DS07 | Can the user control any automatic data sharing, through setting individual sharing preferences in the app? (excluding cookies) No | 6 |
|----------|--|---|
| ORC_DS09 | Is any data (excluding cookie data) shared automatically as soon as the App is accessed – based only on agreement to relevant T&C's or Privacy Policy? Yes | 6 |
| ORC_DS10 | Where/With who is data automatically shared - based only on user agreement to the developer's Privacy Policy and/or T&C's? Developer | 6 |
| ORC_DS12 | What data is automatically shared with the developer? Email, Physical and/or Mental Health Data, General Identifier eg. NHS No, Gender (self-declared or observed), Usage Data, Employment / Career History, Age / DOB, Marital Status / Family / Lifestyle / Social Circumstance, Race / Ethnic Origin | 6 |
| ORC_DS17 | Does the app allow users to access their own NHS personal health records e.g. patient access? | • |
| ORC_DS18 | Does the App appear to access and/or process NHS Patient Information? No | 6 |
| ORC_AI01 | Does the app contain algorithms? Yes | 1 |
| ORC_AI02 | How does the app use the algorithm? The app performs calculations using the users data such as total units, calories and spend. | • |
| ORC_AI03 | Does the app appear to use AI? | 6 |
| ORC_I01 | Is the app designed to provide information or guidance? Yes | 6 |
| ORC_I02 | Does the app provide information that is personalised to an end user's specific circumstances? | 6 |
| ORC_F08 | Does the app provide users with information regarding where they are able to find local or suitable support services? Yes | 6 |
| ORC_F03 | Does the app provide environmental data not specific to the patient? | 6 |
| ORC_EF07 | Does the App provide information, resources or activities to the public, patients or clinicians, either about a specific condition or general health and lifestlye? Yes | 6 |
| ORC_PD01 | Is the data the app collects automatically assessed for the purposes of evaluating risk or providing diagnostic support? No | 6 |

| ORC_DG02 | Does the app diagnose a specific condition? No | • |
|----------|---|------------|
| ORC_DG04 | Does the app provide the option for further assessment or analysis by a healthcare professional? No | • |
| ORC_DG05 | Is the app/does the app include a Symptom Checker? | 6 |
| ORC_TS01 | Does the app contain a clinical calculator? | 6 |
| ORC_MD01 | Is the app intended to be (or does the developer claim it can be) used for the prevention of disease? No | 6 |
| ORC_TS05 | Does the app provide treatment of a condition? No | • |
| ORC_TS07 | Does the app guide the treatment of a condition? | 6 |
| ORC_TS03 | Does the app support healthcare professionals' decisions about treatments? | 6 |
| ORC_TS14 | Does the app automate the treatment pathway for an individual patient? | 6 |
| ORC_TS15 | Is the app intended to be (or does the developer claim it can be) used as a physical intervention to reduce the symptoms or severity of a disease, injury or handicap? | 1 |
| ORC_MD07 | Is the app intended to (or does the developer claim it can be used to) compensate an injury or handicap? No | 1 |
| ORC_CC01 | Does the app predict the fertile window? | (i) |
| ORC_AE20 | Is the App used in combination with drugs or medication? {e.g. medication reminders} | (i) |
| ORC_MN01 | Does the app allow the monitoring of key health information? General Health or Wellness data | (i) |
| ORC_MN02 | Does the app involve the recording of relevant data over time for the user to access and review (with no 'intelligent' manipulation of that data by the app)? Yes | 6 |
| ORC_MN03 | Does the app involve the automated assessment or interpretation of relevant data to deliver alerts, insights, reminders or adjustments regarding the user's health or lifestyle? Yes | • |

| ORC_MN04 | Is the app? a Standard Self Management app? | 1 |
|-----------|--|---|
| ORC_MN06 | Does the app allow others (i.e. not the user) to monitor or view the health data captured? | 1 |
| ORC_TS11 | What type of intervention or treatment does the app provide? Monitoring (basic eg. diary) | 1 |
| ORC_F14 | Can the app be used for patients to have online consultations conversations, or related Health Care services with a healthcare professional? | 1 |
| ORC_AS01 | Is this an administrative app which does not directly impact patient care? | 1 |
| ORC_F13 | Does the app allow users to order and request prescriptions? | 1 |
| ORC_PC01 | Does the App constitute a Pharmacy Service? | 1 |
| ORC_D29 | Does the app send push notifications? Yes | 1 |
| ORC_D30 | Does the app send email notifications? | 1 |
| ORC_F30 | Do any of the features or functions of the app appear to allow it to be used to control a medical device? No | 1 |
| ORC_U19 | Are there opportunities to link with other users (buddying, forums or group education)? | 1 |
| ORC_EF10 | Does the App allow two-way communication between citizens, patients or healthcare professionals? No | 1 |
| ORC_F06 | Does the app provide gamification or goal setting features for the user? Yes | 6 |
| ORC_GS01 | Does the app set goals for the user? Generic | • |
| ORC_U21 | Does the app allow the user to set goals for themselves? | 1 |
| ORC_CUS01 | Can the app presentation be customised by the user? Yes | 1 |

| ORC_CUS02 | Does the app respond to preferences in the device? Yes | • |
|-----------|---|----------|
| ORC_U29 | Is the App totally free? Yes | f |
| ORC_BM01 | How is the app funded? government or similar grants | 1 |
| ORC_U27 | Does the app contain adverts? | i |
| ORC_BF01 | What are the claimed or implied benefits of the app? Other Implied Benefit (please describe) | • |

REVIEW TYPEAPP VERSION OBR - v6.0.0 3.0.19

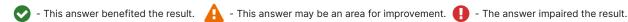
Data

Your Score:

79%

Fundamentals:

Passed









| Question Code | Question and Answer | Impact |
|---------------|---|----------|
| ORC_D39a | Is there a Privacy Policy clearly available via the App/Web App/Website? Yes | • |
| ORC_DP03 | Is the Privacy Policy made immediately available when the user first opens the app? No | A |
| ORC_DP04 | Is the policy made available when the user is signing up to use the services? Yes | ⊘ |
| ORC_DP01 | Is it published within the app? Yes | A |
| ORC_DP02 | Is it available externally via the app? No | A |
| ORC_DP05 | Is it available via the relevant app store? Yes | A |
| ORC_DP06 | What data does the Privacy Policy state the developer collects? Physical and/or Mental Health Data, General Identifier eg. NHS No, Marital Status / Family / Lifestyle / Social Circumstance | • |
| ORC_DP07 | Is the policy accurate, with regards to the data the developer intends to collect? | 0 |

| ORC_DP08 | How does the developer obtain consent for the processing of user data? Clear affirmative acceptance option, separate from acceptance of other terms and conditions and/or consent requests | • |
|-----------|--|----------|
| ORC_DP14 | Does the Privacy Policy Provide the name and contact details of their Data Protection Officer (DPO), or similar individual representative for the company? Yes | • |
| ORC_DP15 | Provide the details of the DPO: KCL Data Protection Officer: Mr Albert Chan (Assistant Director of Business Assurance) Information Compliance team: King's College London, Waterloo Campus Room 5.20, James Clerk Maxwell Building, 57 Waterloo Road, London, SE1 8WA; or by email: info- compliance@kcl.ac.uk | 6 |
| ORC_D69 | Does the developer fully inform the user of how they will collect data about them? Eg. Directly from the user or through third party sources Yes | • |
| ORC_D13 | Does the developer provide users with details on all the purposes of processing user data? Yes | ⊘ |
| ORC_DP10 | What is automatically shared data used for? research | 6 |
| ORC_D38 | Does the developer appear to intend to share or process the user data collected by the app for any purposes that have not been made clear to the user, or for any purposes they deem necessary? No | • |
| ORC_D71 | Does the developer inform users that they would like to use their data for the purpose of marketing, or providing information on products or services that might be of interest to the user? No | • |
| ORC_DP13 | If the user can not opt out of all processing activity, does the developer clearly explain which activities the cannot opt out of and why? Yes | • |
| ORC_D16 | Is the user informed that their data will not be shared with other parties, except for the purposes that have been set out in the privacy policy? Yes | • |
| ORC_DST01 | Does the data privacy policy or equivalent provide detail about where the data collected by the app will be stored (i.e. on the app or in an external data warehouse, cloud server etc.)? Yes | • |
| ORC_DST02 | Where is the data stored? All electronic information will be held securely on encrypted servers. | • |
| ORC_DST03 | Does the Data Privacy Policy, or equivalent, state whether personal data is stored using recognised secure data storage technologies? Yes | A |

| ORC_D17 | Is all personally identifiable data encrypted in transit between the device and any external host storage? Yes | • |
|-----------|--|----------|
| ORC_DM01 | Does the policy state its compliance with recognised International Data Management Standards? (ISO, BSI)? None | A |
| ORC_D19 | Is there a policy or statement that contains details of the length of time data will be retained for? Yes | © |
| ORC_D20 | Is there a policy or statement that details the developer's intentions for data destruction? Yes | • |
| ORC_D21 | Is there a policy or statement that sets out a process for managing data confidentiality breaches? Yes | • |
| ORC_D23 | Is there a policy or statement that confirms the App's compliance with GDPR? Yes | ② |
| ORC_D60 | Is the user informed of the legal basis for which data is collected from them? i.e. Consent, Performance of Contract, Legal Obligation, Vital Interests, Public Interest or Legitimate Interest. Please Specify. Yes | © |
| ORC_DPR03 | Is the user informed that the developer will only collect minimum data items that are necessary to provide their services, therefore ensuring data minimisation principles are met? Yes | ② |
| ORC_D61 | Is there a statement that the policy will be updated if there is a change in the purpose of data collection? This may mean re-obtaining user consent (if consent was the lawful basis). Yes | • |
| ORC_DPR01 | Are users informed of their rights with regards to their data? Yes | • |
| ORC_D93 | Has the developer made the existence of the data subject's right to request that their personal data is deleted clear? Yes | ② |
| ORC_D25 | Has the developer made the existence of the data subject's right to access their personal data clear? Yes | • |
| ORC_D56 | Has the developer made the existence of the data subject's right to rectify their personal data clear? No | A |
| ORC_D81 | Has the developer made the existence of the data subject's right to restrict the use of their personal data clear? Yes | • |

| ORC_D57 | Has the developer made the existence of the data subject's right to object to the processing of his/her personal data clear? Yes | • |
|-----------|--|----------|
| ORC_D59 | Has the developer made the existence of the data subject's right to portability of their personal data clear? No | A |
| ORC_D58 | Has the developer made the existence of the data subject's right to withdraw consent for the use of their personal data clear? No | A |
| ORC_DPR02 | Has the developer made clear the existence of the user's right to request that they are not subject to a decision based solely on automated processing, including profiling, which produces legal/significant effects concerning the user? No | A |
| ORC_D82 | Does the developer provide details that the user can contact them on to exercise their rights? Yes | Ø |
| ORC_D83 | Is the user informed of the time frame in which the developer will respond to any requests to exercise their rights? This time frame should be within two months of receipt of any request. | A |
| ORC_D44 | Is the app 'particularly likely' to be used by children, even if they are not the primary market for the app? No | 6 |
| ORC_DO01 | Are users informed of how they can report, to the developer, any knowledge of a child accessing the app and providing personal data, without parental consent? Yes | • |
| ORC_D91 | Is the user made aware that by following links to third party websites, the developer's policies no longer apply and that the user should make themselves aware of the third party's policies? Yes | ② |
| ORC_D92 | Is the user informed of how they can make further enquiries about the company's privacy policy? Yes | ② |
| ORC_D06 | Does the app allow the user to set their preferences for sharing the app data with or from other apps (e.g. Facebook / Instagram/Fitbit etc)? No | A |
| ORC_DO02 | Is it strictly necessary for anyone to easily access the information that persists on the app? eg. to access health info during an emergency No | 6 |
| ORC_DO03 | Are users provided options to introduce additional security measures to protect their data on the app? eg. set additional pass codes for access to the app, after accessing the device is unlocked. No | A |

| ORC_DO04 | Does the app use a sign up/sign in verification/authentication model? Yes | • |
|----------|--|---|
| ORC_DO05 | What type of model is being used? | |
| | One-step email authentication, HCP Granted Access/Invite | |

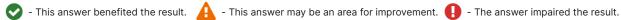
Usability & Accessibility

Your Score:

85%

Fundamentals:

Passed









| Question Code | Question and Answer | Impact |
|---------------|--|--------|
| ORC_DE01 | Is there a statement within the app outlining compliance with any currently recognised app design standards? None | A |
| ORC_DT01 | Is there a statement within the app or store about user feedback during design and/or development? Yes | • |
| ORC_DT02 | Is there a statement either in the app or store about user involvement in testing? Yes | • |
| ORC_U04 | Can the user change the font size within the App or does the app respond to font preferences in the device? Yes | • |
| ORC_U07 | Does the app provide support options for users with poor sight? Yes | • |
| ORC_U08 | Does the app provide support options for users with hearing difficulty? Yes | • |
| ORC_U06 | Can the user change the presentation theme? Yes | • |

| ORC_U32 | Does the app include the following functions: Home/Menu button, Help/About button | 1 |
|----------|--|----------|
| ORC_U15 | Are any clinical or technical terms used explained clearly to the user? (either within the content of the app or via a glossary) Yes | • |
| ORC_D31 | Does the user have options to manage the notification settings for push/email notifications within the app for convenience/privacy? Yes | • |
| ORC_D32 | Does the app inform the user how to manage notification settings for convenience / privacy (eg to prevent divulging personal information if the device is locked but on show?) Yes | • |
| ORC_U23 | During review, was there any evidence of bugs? No | ② |
| ORC_U24 | Is there any statement or evidence of how to report issues to the developers? (e.g. this may be a help button with contact form, instructions or email details) Yes | 1 |
| ORC_U33 | What kind of support is offered? eTicket | • |
| ORC_U25 | Is there any statement within the app about the developer's commitment to addressing problems reported to them? (e.g. timescales to respond, commitment to eradicate reported bugs and faults) No | A |
| ORC_UX01 | Does the Developer publish or make available unedited User Feedback Data? No | A |
| ORC_UX02 | Does the Developer publish or otherwise make available any unedited user usage Data? | A |

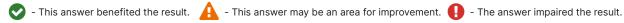
Professional Assurance

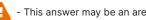
Your Score:

80%

Fundamentals:

Passed









| Question Code | Question and Answer | Impact |
|---------------|--|------------|
| ORC_MD11 | Is the app a medical device? (autofill but there to validate) No | • |
| ORC_FDA01 | Has the app been FDA approved? | 6 |
| ORC_FDA02 | Has the app been FDA cleared? | 1 |
| ORC_ESF05 | Is the app ESF Tier 3b? | (1) |
| ORC_ESF04 | Is the app ESF Tier 3a? | i |
| ORC_ESF03 | Is the app ESF Tier 2b? Yes | i |
| ORC_ESF02 | Is the app ESF Tier 2a? | i |
| ORC_ESF01 | Is the app ESF Tier 1? | f |

| ORC_EE02 | What type/s of evidence is available? RCT | • |
|----------|---|------------|
| ORC_EE14 | How many pieces of evidence does the app provide? One | (1) |
| ORC_EE13 | How many RCT's and/or observational studies does the app have? One | (1) |
| ORC_EE10 | What category does the evidence relate to? Alcohol consumption | (1) |
| ORC_EE11 | What benefit does the evidence relate to? Reductions in alcohol consumption | 6 |
| ORC_EE03 | Provide links to the publicly available evidence/published evidence that the developer has provided. 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.researchprotoce19720ols.org/2020/10/ | 1 |
| ORC_EE04 | Is the sample size appropriate? Yes | 6 |
| ORC_EE05 | Does the evidence found provide a p-value or Confidence Interval (CI)? Yes | • |
| ORC_EE06 | Does the P-Value demonstrate significance (p<0.05)? Yes | 6 |
| ORC_EE07 | Is there a comparator? Yes | (1) |
| ORC_EE08 | Is the comparator validated? No | (1) |
| ORC_PB01 | Is there a suitably qualified Professional involved in the Development team of the App? Yes | • |
| ORC_PB02 | Has the app been developed by a recognised or national health body? Yes | • |
| ORC_PB03 | Is there evidence of an endorsement by a relevant body? | A |
| ORC_PB04 | Are organisations using the App? No | A |
| ORC_PB05 | Is there a statement that it has been positively evaluated or validated by a relevant healthcare professional? No | A |

| ORC_PB06 | Is there evidence within the app that the developer has validated any guidance with relevant reliable information sources or references? Yes | • |
|-----------|---|---|
| ORC_S01 | Does the Developer clearly identify who the app should be used by? Yes | • |
| ORC_S02 | Does the Developer publish their risk management processes? | A |
| ORC_S03 | Does the Developer make clear risks associated with using the app? No | A |
| ORC_S04 | Is there a way for the user to confirm that the data input is accurate? No | 0 |
| ORC_S05 | Does the Developer list a Clinical Safety Officer on/in any relevant sites/content? No | A |
| ORC_ESF06 | Has the app met Tier 1 minimum requirements? Yes | A |
| ORC_ESF07 | Has the app met Tier 2a minimum requirements? Yes | A |
| ORC_ESF08 | Has the app met Tier 2b minimum requirements? Yes | • |
| ORC_ESF09 | Has the app met Tier 3a minimum requirements? Yes | A |
| ORC_ESF10 | Has the app met Tier 3b minimum requirements? No | A |
| ORC_ESF11 | Does the app have appropriate evidence for the ESF tier? Yes | 6 |

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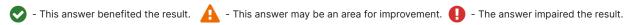
Android

3.0.19

Reviewer **Comments**

Fundamentals:

Passed









| Question Code | Question and Answer | Impact |
|---------------|--|--------|
| ORC_RC01a | Would you like to provide any additional review notes for the sign off and/or further discussion? No | 6 |
| ORC_RC02a | Would you like to provide any additional app review notes to be displayed on the developer report and website? No | 6 |