**RESEARCH PROTOCOL**

***Full Title: Digital health intervention for the management of ascites in patients with chronic liver disease***

***Short Title: My Liver Health App for Ascites***

**STUDY INVESTIGATOR(S)**

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# INTRODUCTION

Chronic liver disease (CLD), characterised by complications such as ascites, encephalopathy, variceal bleeding, and hepatocellular carcinoma, is a major health concern in Australia. While effective evidence-based therapies exist, delivery of this care has been proven to be sub-optimal. Smartphone-based technologies represent a promising tool for effective disease management and improving patient engagement. Indeed, real-time data collection has demonstrated feasibility and acceptability in a variety of conditions—from schizophrenic disorders (1) and diabetes (2), to some promising initial work in liver health (3-5). However, in the context of ascites management, while modelling of this type of intervention has shown cost-effectiveness and the ability to make timely, readmission reducing interventions (6), there is a need for real-world trials to explore the feasibility and utility of this at scale (7). The objective of this study therefore is to determine the feasibility of a smartphone-based application in the management of ascites in CLD patients in our hospital and community setting.

# BACKGROUND

CLD is a progressive disease process leading to liver fibrosis and cirrhosis. Cirrhotic patients may remain compensated with stable liver function but further or ongoing insults to the liver may result in further decline of liver function and decompensation. Decompensated cirrhosis/CLD is characterised by a number of clinical complications including ascites, encephalopathy, variceal bleeding, and hepatocellular carcinoma. Increasing CLD-related mortality rates (8) and CLD-related hospital admissions (9) are reported in Australia and many developed countries. The disorder is not only common but also expensive and challenging to manage, characterised by frequent, prolonged, and costly hospital readmissions.

Effective, evidence-based therapies have been shown to improve survival in CLD patients, however, available data suggests that the delivery of care is suboptimal. The reasons for this are complex and multi-factorial. Smartphone technology offers a new and innovative approach to the management of chronic diseases by shifting care to a patient centred model. According to the Mobile Consumer Survey conducted in 2020, approximately 92% of the Australian population own a smartphone (10), showcasing the dominant role of smartphones in our lives. The use of digital health management tools has the potential to reach patients in the community, integrate data collection into their daily activities, and provide improved education and reminders. These technologies provide an opportunity to overcome many of the challenges and limitations associated with chronic disease management.

In recent years, a number of smartphone-based apps have been developed to help manage chronic diseases such as mental health conditions (1, 11), diabetes (12, 13), chronic lung disease (14, 15), and cardiovascular disease (16), with results showing the potential of these apps to improve health outcomes in patients through the implementation of self-care plans and enhanced symptom control. CLD would be a logical choice for digital health style interventions. A recent study of patients with decompensated cirrhosis reported that 78% patients would consider using a smartphone application to manage their cirrhosis (17), while in another study 61.5% of patients with cirrhosis indicated they would be interested in using an online health management program (18). An app focused on the management of hepatic encephalopathy (HE) in cirrhotic patients, the Patient Buddy app, demonstrated that using the app to monitor medication adherence and critical values such as weight and cognitive assessments allowed eight HE-related readmissions to be avoided (19). Similarly, another recent study demonstrated excellent patient and provider engagement when using a smartphone-based app for the outpatient management of ascites (20), while further modelling predicted that telemonitoring is a cost effective way to manage ascites (6). These studies indicate that smartphone-based monitoring may be successfully used in CLD management. Furthermore, it has the potential to make patients feel better supported to manage their chronic disease outside of the hospital.

A major cause of CLD related readmissions is ascites. It is also associated with poor health-related quality of life and high cost of care. Body weight measurement has been identified to be a good indication of ascites volume, with monitoring of weight changes central to current clinical practice in ascites management. Early identification of weight changes signals changes in ascites volume, allowing for interventions such as diuretic dose modification, large-volume paracentesis, and laboratory workups to identify other related complications. However, there is currently no convenient method for the transmission of accurate weight data from patients to their care providers that enables early intervention and prevents readmissions. Additionally, it is important to encourage limiting salt intake and understanding mood factors that may worsen engagement with these lifestyle factors.

This project will be conducted with Digital Health Researchers in the College of Medicine and Public Health (Flinders Digital Health Research Lab) at Flinders University, who have developed the Mindtick app (11). The app collects self-reported mood, physical health, and activity data. It also collects sensor data, and encourages engagement with activities related to pleasure or mastery (21). It displays this data on a dashboard, which flags to case managers the directionality of each measured parameter and whether there are any indicators that require immediate attention. We have adapted the Mindtick app to be trialled in a CLD management setting, in particular ascites management. Patients will be able to transmit daily weight data via the My Liver Health app. Additionally, the app will be used to monitor medication adherence, send out reminders, and provide patients with additional education and information on self-management of their ascites. Thus, the aim of this study it to evaluate the feasibility of a smartphone-based application in facilitating ascites management in patients with CLD.

# AIM OF STUDY / RESEARCH QUESTIONS

To evaluate the feasibility of a smartphone-based application in facilitating ascites management in patients with CLD.

As a secondary aim, this study aims to develop a dashboard that allows the clinical care team to follow patient self-management and assess the functionality of this dashboard in supporting patient care.

# STUDY DESIGN AND LOCATION

This is a feasibility study to be conducted at the Flinders Medical Centre (FMC), within the Department of Gastroenterology and Hepatology. This project will be conducted in conjunction with the Flinders Digital Health Research Lab in the College of Medicine and Public Health at Flinders University.

Each patient participant will participate for 6 months. The aim is to enrol thirty patients into the study.

# ELIGIBILITY CRITERIA

1. **Inclusion Criteria**

* Age ≥ 18 years
* Ability to provide informed consent
* Patients with cirrhotic ascites requiring active management
* Patient owns an android or iOS compatible smartphone
* Patient is able to use a smartphone device at a basic level

1. **Exclusion Criteria**

* Patient with severe cognitive impairment
* Patients with insufficient command of the English language to be able to understand the instructions
* Patients who do not have, or are unable to use, a smartphone device
* Patients under active management by Palliative care services or an expected survival of <3 months

# STUDY OUTCOMES

1. **Quantitative**
2. **Primary Outcome(s)**

* The percentage of days with weight data transmitted successfully to care team.
* The number of weight alerts that prompted responses from the care team.

1. **Secondary Outcome(s)**

* The percentage of patients that required diuretic dose modification.
* The percentage of patients that required admission for large volume paracentesis/ascites (compared with control group of ascites patients).
* Number of liver related emergency admissions (compared with control group of ascites patients).
* The number of contacts with care team independent of triggers from the app.

1. **Qualitative**
2. **Primary Outcome**

The primary outcome measure of the qualitative review is to evaluate the benefits and barriers to the intervention.

1. **Secondary Outcome(s)**

* Analyse patient satisfaction with the smartphone application.
* Analyse care teams experience in regard to usability of the dashboard.
* Evaluate the desired features of the ascites management app.

# STUDY PROCEDURES

1. **Recruitment of participants**

Pre-screening: A list of patients with cirrhotic ascites requiring active management will be identified from the Chronic Liver Programme database, a service provided by the Hepatology Unit at Flinders Medical Centre.Under National Statement 2.3.10 a, b, d, e, f, we wish to apply for a waiver of consent to access a patient’s personal information for research purposes, in order to identify suitable participants for this research project. The study coordinator will be required to access medical records to determine eligibility prior to obtaining consent from the patient. It is not feasible or appropriate to discuss screening with potential participants to access medical records. Due to the distress that consent processes may cause to a patient and/or their family, it is imperative to establish eligibility prior to burdening families with complex study information. Formal consent will be obtained from potential participants if a patient is deemed to be eligible for this study. The study coordinator in charge of pre-screening will have access to confidential patient information as part of their employment.

Consent: Eligible participants identified during pre-screening will be sent an invitation letter to consider taking part in this study, along with a copy of the participant information and consent form. Potential participants will have the opportunity to contact the trial team for further information. The information sheet will include details of the purpose of the study, the duration, and the app being used to obtain study data. One of the CLD nurses, who is part of the participant’s care team, will contact the potential participant after a week to follow-up and determine whether they are interested in taking part in the study. If the patient agrees to taking part in the study, a clinic appointment will be made for the patient to attend the hospital to sign the consent form and have their orientation session. If a patient declines, they will be given the option to state that they are not approached again for this study. All responses will be recorded in our pre-screening log to ensure that participants aren’t re-approached. Participants will have the option to withdraw from the study at any time. A total of thirty consecutive patients requiring active management of cirrhotic ascites will be offered the opportunity to participate in this feasibility study. Informed consent will be obtained at a trial appointment, where the potential participant will be provided with additional opportunity to ask any questions. Consent for the qualitative interviews will be obtained at the same time.

Upon informed consent, the study coordinator will download the app on to the participants’ phone and show the participant how to use the app and record the required study information. Participants will also receive the My Liver Health User Guide and be provided a smart scale equipped with wireless data transmission capabilities to be used for the duration of the study.

1. **Study design**

Participant monitoring and feedback: Self-monitoring of weight using digital scales is a recommended self-management tool for patients with ascites. Upon consenting, participants will be asked to use the My Liver Health app to record their weight via the smart scales provided and answer questions regarding dietary salt intake, whether they have taken their medication, and how they are feeling **daily**. Participants will be asked to weigh themselves at a set time every day in the morning. Participants will also be asked to answer two questions about their general wellbeing **weekly**. Participants will be expected to record their weight and answer the daily questions over the weekend. If participants experience unmanageable pain, increased shortness of breath or a fever over the weekend, they will be asked to attend the emergency department. Emergency contact details will also be provided at the end of the daily check-in page and the bottom of each Action Plan page within the My Liver Health app.

The smartphone application will be used for three major functions: (i) collect data recorded by the patient, (ii) send prompts to participants to comply with recording daily weight and answer questions related to their ascites self-management, and (iii) provide participants with educational and activity-focussed resources for better self-management of their ascites. The education and activity-focussed resources will be algorithmically curated content designed and approved by clinicians (FMC Cirrhosis Booklet used in SOC). Participants will be provided with emergency contact details at the end of the daily questions, and in each of the education resource pages, should they need to contact the Chronic Liver Disease service. All participants will be rewarded with a $30 gift card for participating at the end of the study.

Gamification: To encourage participation, we have designed a simple gamification component to the intervention. This design is in line with recent work exploring the long-term benefits to adherence using small rewards, even after those rewards have ceased (22). All participants will receive a $30 gift card for participating at the end of the trial. In addition to the $30 gift card, five $50 gift cards will be available to be won based on a lottery system, where entries will be determined based on a variable ratio schedule of reward for completing the intervention daily. Every participant will begin with one entry in the lottery. From then on, each time the participant completes a daily check-in they have a random chance of earning an additional entry into the lottery, with a maximum of one entry per day. It will be made clear that entry into the lottery will only be possible upon completion of the daily check-in requirements, and that logging into the app multiple times a day will not result in additional entries into the lottery. At the end of the intervention, a random number generator will select the five winning entries, meaning those who participate more regularly have a *higher* chance of winning, but all participants have *a* chance of winning.

Clinical dashboard system for monitoring engagement and clinical use: The care team will have access to a dashboard that graphically displays gathered data (11). Weight changes described in Table 1 will prompt the care team to follow-up with the participant and intervene where necessary, such as scheduling a paracentesis appointment, modify the diuretic dose or request a laboratory workup. Alerts related to weight change are customisable and will be assigned based on the patient’s disease severity, such as if the patient has oedema. If no weight data has been recorded by the smart scales for two or more days, reminder push notifications will be sent to the patient via the application. After a further two days, SMS reminders will be sent. Data of participants with either no weight recorded or those with a significant weight change will be visible at the top of the dashboard, thus assisting the care team to determine which patients require urgent follow-up.

*Table 1: Customisable weight alerts on clinical dashboard*

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| **Constant Alerts** |
| Gains more than 3kgs over 3 days |
| Gains more than 5kgs over 1 week |
| **Additional alerts for patients without oedema** |
| Loses more than 0.5kg in 1 day |
| Loses more than 1.5kg over 3 days |
| **Additional alerts for patients with oedema** |
| Loses more than 1kg in 1 day |
| Loses more than 3kg over 3 days |

The dashboard will be monitored by the study care team daily at a time when most (or all participants) have weighed themselves. The dashboard will not be monitored on weekends, and this reflects current standard practice. Data entered over the weekend by patients will be followed up by the CLD nurses on the following Monday and action taken as required.

Tech monitoring/support: All electronic data will be stored in encrypted format and on secure servers and computers in accordance with Australian legislation. Only the researchers involved in this project will have access to this data.

Qualitative interview: Participants will be oriented to the app in a session facilitated by members of the study team. These sessions will be recorded, transcribed verbatim, and field notes taken during and after each session. This qualitative data will inform part of the feasibility and utility results of the trial. It is crucial to examine onboarding and familiarisation experiences with mobile health (mHealth) apps. Learnability, satisfaction with user experience, and lack of errors have all been identified as core to the successful design of mHealth apps (23), and this approach allows us to manage any potential teething problems that might inhibit long-term engagement with the intervention, continue to refine the app based on feedback, and report to other designers in the field on our findings. A set of standardised questions will be asked from each participant (Appendix I). The remainder of the session will follow the structure of the My Liver Health User Guide and will remain open ended and carried out as a conversation to allow for the participant to provide insights that may not have been anticipated by the research team. It is anticipated that this session will be approximately 20-40 minutes.

Qualitative feedback will also be sort from all participants at the end of the study. All interviews will be conducted in-person at an end of study trial visit. The interview will be audio-recorded and transcribed verbatim, and field notes will be taken during and after each interview. One researcher, not part of the core research team, will conduct all the interviews. The designated interviewer will be provided a set of standardised questions to ask the participants (Appendix II) during the interview. The interviews will be open ended and carried out as a conversation to understand the participant's experience using the smartphone application. It is anticipated this session will be approximately 15 minutes. Participants will also be asked to complete a satisfaction survey (Appendix III) during this session which will take approximately 5 minutes.

End of study: The My Liver Health app will be disabled at the end of study and participants will be notified that their care will return to standard protocol with their care team. This information will be conveyed to the patient via the PICSF and during the My Liver Health orientation session. Participants will also be asked to return the provided smart scales at their final interview session.

1. **Methods of data collection**

Multiple demographic (age, gender) and clinical (aetiology of disease, MELD score, Child-Pugh score, treatment experience) variables will be obtained from medical records (hardcopy and electronic).

Data entered into the My Liver Health app, and collected by the smart scales, will be accessible on the clinician dashboard. This data will be accessed by the study team during and at the end of study for analysis. Each study participant will be required to answer the following questions **daily**:

* Have you weighed yourself today?
* Have you taken your medication today?
* Have you maintained a no added salt diet?
* How do you feel at the moment?

Each study participant will be required to answer two brief questions relating to their general wellbeing on a **weekly** basis:

* Have you had the energy to do the things you want?
* How well have you been sleeping this week?

Hospital admissions data will be obtained for each participant at the end of study through the Clinical Epidemiological Unit at FMC. The Clinical Epidemiology team will provide the data to the researcher for analysis through a secure encrypted share folder routinely used for the transfer of data.

Weight change triggers for each participant will be recorded by the dashboard, as well as by the study care team in a password protected spreadsheet. Similarly, all symptoms related to weight triggers/changes, will be recorded on the My Liver Health app/dashboard via the participant’s responses to the daily questions. The care team will also record the number of active interventions required for each participant, where active interventions include communicating directly with the participant, modifying the diuretic dose, scheduling a paracentesis appointment, or requesting a laboratory workup.

# DATA ANALYSIS

1. **Quantitative**

Statistical analysis of the app data will be performed after collecting data from all participants in this study. There will be no interim analysis. Where possible, missing data will be imputed. For example, missing mood, or activity data can be inferred from data of previous or following days, previous data from the same day of the week, etc. The procedure and amount of imputed data will be detailed in the final report. A clustering analysis will be performed on the final data, grouping patients’ engagements with the intervention and clinical outcomes as appropriate. A Cox Regression will be performed to investigate time-to-event differences between patient clusters, and to inform potential forecasting algorithms for future studies in this area. Descriptive statistics will be used to examine the demographic information.

1. **Qualitative**

Recordings of interviews will be allocated a unique study ID prior to being sent for transcription. All data will be assigned a unique study ID and will be stored securely, in a password protected computer and only FMC study investigators will have access to the data. Hardcopies of the transcriptions will be kept in a secure locked filing cabinet in the Hepatology Department research office at FMC. Participants will be given the option of requesting the transcript to check their answers.

A qualitative approach will be used to analyse the collected data as described in grounded theory. This approach for content analysis is interpretive in nature and used to describe or illuminate a phenomenon through identification of manifest (the obvious) and latent (underlying meaning) content in a text. This will involve: (1) reading of the text several times to become familiar with it and reflect upon the content, (2) identification in the text of meaning units that describe the phenomenon, (3) meaning units condensed and essential content is abstracted and labelled with a code, and (4) codes compared based on similarities and differences sorted into themes. Coding and sorting of themes will be assisted using the analysis tool NVivo (QSR Software, 2021).

# DATA HANDLING AND RECORD KEEPING

1. **Data Collection and Management Responsibilities**

Data collection is the responsibility of the research staff of FMC under the supervision of the Principal Investigator. The Principal Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All electronic data will be collected through the relevant smartphone application subject to the terms and conditions of the smartphone app or service provider. These terms are outside the control of the researcher. Custodianship for the data will commence when it is accessed and downloaded by the research team. All electronic data will be stored in encrypted format and on secure servers and computers in accordance with Australian legislation. Only the researchers involved in this project will have access to this data.

1. **Study Records Retention**

The CLD nurses involved in the patient’s care will have access to identifiable information. Patient data extracted from the dashboard will be de-identified and will be labelled with a unique study number. De-identified study data will be entered into an Excel spreadsheet and stored in a secure, password protected computer. Only study investigators will have access to the de-identified study data. Data will be stored for a maximum of 15 years as per NHMRC guidelines, and after this time it will be erased/destroyed.

1. **Protocol Deviations**

A protocol deviation is any noncompliance with the study protocol, GCP, or HREC requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be implemented promptly.

The principal investigator will use continuous vigilance to identify and report deviations within 72 hours of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the approving HREC(s) and site Research Governance Officer(s).

# STUDY TIMELINE

The study is expected to commence in March 2022, upon ethics and governance approvals and app development, and completion anticipated by December 2022. Recruitment is expected to take 2 months, with study duration expected to be 6 months. Data collation and analysis is expected to take a further 2 months.

# ETHICAL CONSIDERATIONS

1. **Confidentiality**

Electronic de-identified data will be stored on SA Health servers in secure folders accessible to only staff/investigators of the Hepatology Unit at Flinders Medical Centre. All computers will be two-level password protected. Confidentiality will be maintained beyond study parameters.

1. **Risks and benefits of the study**

Risks: It is assumed that the use of the My Liver Health app poses minimal risk to patients. It is possible that some patients may find it difficult or upsetting to be asked to think about their disease on a daily basis and assess their mood on a weekly basis. Participants will be provided the contact number for the CLD nurse in the PICF, as well as at the end of daily check-in page of the My Liver Health app, should they feel any discomfort and wish to talk to the study team. However, the risk of this occurring is assumed to be no more than that encountered during an appointment or routine phone call with their CLD nurse. Since this study is embedded in clinical care with an intention to augment routine practice, there is an expectation that there is a rapport in the therapeutic relationship where the patient feels confident to provide any concerns or feedback.

Benefits: It is possible that patients may develop a better understanding of their symptoms and disease through the visualisation of their daily weight and from the educational resources provided on the app. This research is observational and does not involve any form of intervention in care unless prompted by weight changes recorded by the smart scale as judged by the monitoring care nurse, which would be expected to increase participant safety compared to normal procedures.

1. **Ethical Review**

The study will be conducted in full conformance with principles of the “Declaration of Helsinki”, Good Clinical Practice (GCP), the National Statement on Ethical Conduct in Human Research (NHMRC, 2007), Australian Code for the Responsible Conduct of Research (2007) and within the laws and regulations Australia.

Ethical approval from the following HRECs will be obtained:

* Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC)

Any future use of the data collected in this study for a new research purpose will be subjected to HREC approval.

1. **Site/Governance Review**

In accordance with the *SA Health Research Governance Policy Directive,* Site Specific Assessment (SSA) Approval will be sought from individual public health sites where the project is being conducted, including:

* Flinders Medical Centre, SA

# STUDY OUTCOMES AND SIGNIFICANCE

Ascites is a common, painful, and serious complication of liver cirrhosis associated with poor quality of life and high hospital admissions. Body weight monitoring is the standard practice for monitoring ascites volume, however, convenient mechanisms to transfer this information between the patient and their care provider doesn’t exist. This study aims to address this issue by adapting the established Mindtick app to enable ascites management.

We anticipate that results from this study will demonstrate a reduction in emergency ascites admissions to hospital through the timely management of symptoms via the My Liver Health app, particularly through the transmission of daily weight updates to the clinical care team. Patient adherence to daily weight checks and self-management of their disease is believed to increase as the My Liver Health app allows for learning about liver disease and through the knowledge that they have increased access to clinical care via a patient centred model of care.

Additionally, the data around which educational materials are accessed in the app will also provide insights into lifestyle factors that patients identify as most needing education. This could aid care management teams in targeting care and education to patients before adjustments to diuretics or scheduling paracentesis is necessary.

Long term, dependent on outcomes of this feasibility study, we hope to conduct a multicentre, randomised control study to investigate the benefit of smartphone technology on the management of other CLD complications, as well as determine the uptake of this technology by patients. This has the potential to revolutionise management of CLD in Australia and allow for more effective utilisation of hospital and community resources.

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**APPENDIX I – Qualitative Interview Questions (Orientation session)**

1. Have you participated a trial like this before?
   1. What and when have some of those occasions been?
   2. Can you describe to me why you participate in studies such as this one?
2. Are you a “techie” person?
   1. What do you use tech for in your daily life?
   2. Shifting to Digital Health tools, can you describe to me your history of using them?
3. How do you currently manage your Cirrhosis? Maybe tell us about your daily routine, if you have one.
4. How do you think technology designed to monitor your symptoms, weight, and medication adherence – as well as provide you with information about how to best manage your cirrhosis – might fit in your day-to-day life?
5. What does the ideal outcome of participating in a study like this look like to you?

**APPENDIX II – Qualitative Interview Questions (End of Study)**

1. Tell me about your experience of having your liver disease managed via the My Liver Health app.
2. What felt different about you care, if anything, because of the My Liver Health app?
3. What were some of the good things about using the My Liver Health app?
4. Do you have any concerns about using the My Liver Health app to manage your care?
5. Do you have any other feedback about the use of the My Liver Health app to manage your liver disease care?
6. Do you think it is realistic to expect other patients with CLD to use the My Liver Health app in the future?

**APPENDIX III – End of Study Satisfaction Questions**

Please help us by answering some questions about your experience with the My Liver Health app. We are interested in your honest opinions, whether they are positive or negative.

1. **The My Liver Health app was easy to use**.

Strongly Disagree Disagree Neutral Agree Strongly Agree

1. **Technical difficulties were not a major problem and did not interfere with using the My Liver Health app.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

1. **The My Liver Health app was helpful in reminding me to check my weight daily.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

1. **The My Liver Health app was useful in reminding me to take medication.**

Strongly Disagree Disagree Neutral Agree Strongly Agree

1. **The additional resources were useful**.

Strongly Disagree Disagree Neutral Agree Strongly Agree

1. **I felt confident that my liver disease was being managed well by the liver team using the My Liver Health app.**

Strongly Disagree Disagree Neutral Agree Strongly Agree