Final report

August 2017

Innovating for Improvement

AlcoChange – A Smartphone Tool to Reduce Alcohol Use and Admissions in Alcoholic Liver Disease

Royal Free London NHS Trust

The Health Foundation

About the project

Project title:

AlcoChange – A Smartphone Tool to Reduce Alcohol Use and Admissions in Alcoholic Liver Disease

Lead organisation:

Royal Free London NHS Trust

Partner organisation(s):

CyberLiver Ltd (SME)

Project lead(s):

Gautam Mehta, Kevin Moore

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Part 1: Abstract

Introduction: Alcohol contributes to over 5% of deaths worldwide, and death rates from alcohol-related liver disease (ARLD) in the UK continue to rise sharply. On-going alcohol use in ARLD leads to markedly increased mortality (Thursz et al, 2015). However, there are no effective pharmacological therapies for maintaining abstinence. Behaviour change interventions (BCIs) are effective psychological tools for reducing alcohol use, but are difficult to scale widely.

Aims: The aims of this project:(i) to develop a smartphone app and breathalyser (AlcoChange), to facilitate self-monitoring and deliver BCIs in response to patient triggers, and (ii) to undertake an open-label pilot study of AlcoChange in 60 patients with ARLD, to determine compliance with the app/breathalyser and changes in self-reported alcohol consumption.

Implementation: AlcoChange was developed following feedback from alcohol service users. AlcoChange allows monitoring of craving, alcohol consumption and breath alcohol, and provides motivational messaging in response to patient triggers.

The pilot study involved recruitment of inpatients/outpatients at Royal Free London with ARLD and recent alcohol use. The inclusion criteria were: intent to maintain abstinence, possession of compatible smartphone. The exclusion criteria were Child-Pugh score >7, inability to provide consent. Participants were assessed at baseline and 3-months. The primary endpoint was self-reported alcohol use (units/week, timeline follow-back).

Impact: Twenty participants completed the baseline and 3-month visits. Six subjects were lost to F/U, and one died. Self-reported alcohol intake showed a trend to reduction at 3-months (87.1±18.4 *vs* 46.7±15.4, p=0.09). Following sub-group analysis for compliance with the app (>20 logins over 3 months), compliant participants reduced alcohol consumption, whereas non-compliant participants increased (-52.1%±19.0% *vs* +30.7%±41.8%, p=0.10).

Conclusions: This study demonstrates that a smartphone app/breathalyser can be used for self-monitoring and BCIs in patients with ARLD, with a ‘dose effect’ amongst compliant patients. Smartphone apps are a scalable intervention to help maintain abstinence in ARLD. This study remains open, with further data to present. Future opportunities include use of AlcoChange in a NIHR clinical trial application, and engagement with local commissioners to embed AlcoChange in alcohol services.

Part 2: Progress and outcomes

This project was initiated with the aim of developing and testing a smartphone tool to help patients with alcohol-related liver disease (ARLD) reduce their alcohol intake and maintain abstinence. In the UK, ARLD causes almost all (86%) of the directly attributable mortality from alcohol, and hospital admissions and mortality rates continue to increase year on year. On-going alcohol use after hospital discharge remains the single most important determinant of long-term mortality in severe ARLD. Studies indicate that 48%-65% of patients with ARLD resume alcohol use, and only 10-25% engage with alcohol reduction treatments.

Behaviour change interventions (BCIs), e.g. brief intervention, are effective tools for reducing alcohol consumption, but are difficult to scale widely and not always delivered at a time when the patient is receptive. AlcoChange was developed as a smartphone app and breathalyser, to facilitate self-monitoring of alcohol use/abstinence and to deliver BCIs. The app was designed with feedback from alcohol service users. Specifically, the BCIs are delivered in real time, in response to patient triggers such as cravings or geographical location. Screenshots to illustrate the flow of the app are provided in appendix 1.

The aim of this pilot study was to determine compliance with the app, and to obtain pilot data on effectiveness in reducing self-reported alcohol intake over a 3-month intervention period.

The major limitations in the progress of this project were: (i) the delay in initiation of the study due to problems with ethical approval, and (ii) the lack of smartphone use amongst the ARLD patient population. Both of these limitations are discussed in detail in section 4.

The process of screening and recruitment at Royal Free Hospital (RFH) is outlined below (figure 1). Patients were pre-screened for an alcohol-related diagnosis from outpatient clinics and current inpatient lists. They were subsequently approached in a clinical setting to determine if they were in possession of a smartphone, had pre-existing liver disease with on-going alcohol use, and were willing to provide informed consent to participate. Visit 1 was conducted in person at RFH, and comprised baseline interview, alcohol history, app download and education session. Visit 2 was conducted at 3 months, either in person or over the telephone, and comprised alcohol history and qualitative feedback on use of the app/breathalyser. All participants were also reimbursed £30 at visit 2, for participation and mobile data costs.

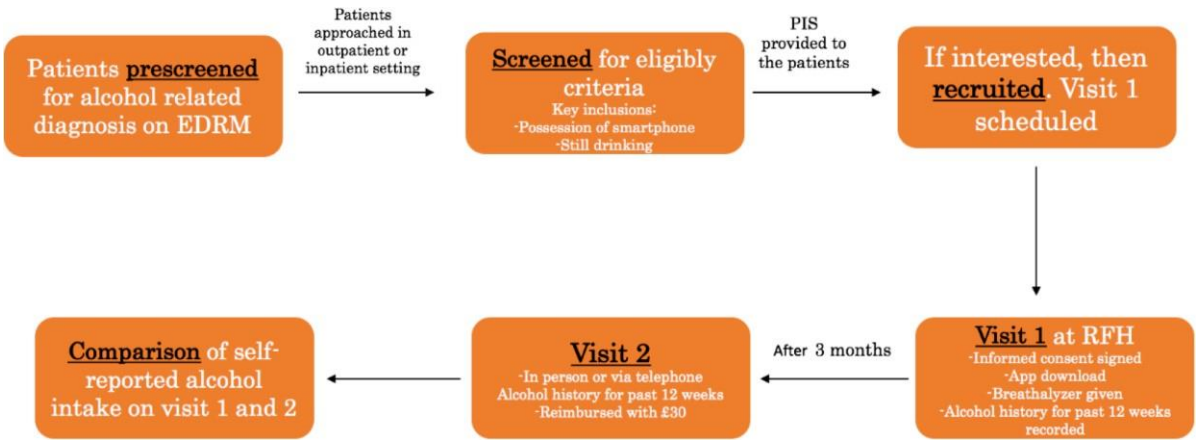

Figure 1: Patient screening, recruitment and follow-up.

Rates of recruitment to the study were low throughout the study period. At the time of writing this report, 232 patients had been screened for participation in the study. Of these, 46 have been recruited (19.8%), and the remaining 186 either did not wish to participate or did not meet the eligibility criteria. The most common reason for non-participation was lack of a smartphone (50%) – figure 2a.

Of the 46 patients recruited, 20 have completed the 3-month study period, with data to analyse from visit 1 and 2. This data was analysed on a per-protocol basis. The flowchart of recruited participants is shown in figure 2b.

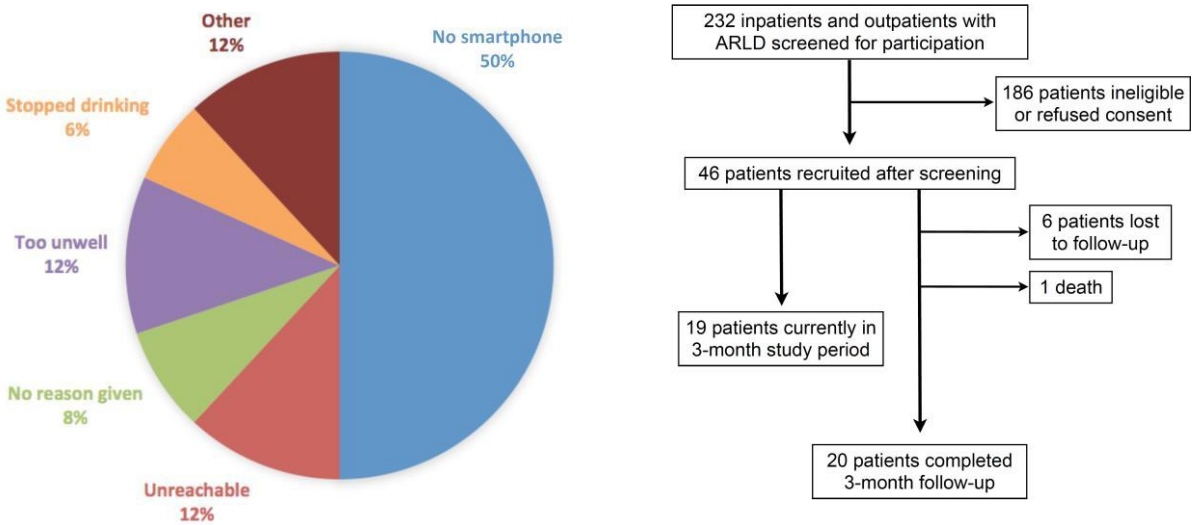

Figure 2a *(left panel)*: Reasons for non-participation following screening. Figure 2b *(right panel)*: Flowchart of recruited participants.

Follow-up data from the 20 participants completing the 3-month study period is presented in figure 3. Mean alcohol use decreased across the study cohort, from 87.1±18.4 units/week to 46.7±15.4 units/week (p=0.09).

Importantly, a 'dose-response' was seen amongst individuals who used the app and those who did not. A sub-group analysis for compliance with the app (>20 logins over 3 months) demonstrated that compliant participants *reduced* overall alcohol consumption by 52.1%±19.0%, whereas non-compliant participants *increased* by 30.7%±41.8% (p=0.10). A total of 5 participants (20%) were completely abstinent at the end of the 3-month period; 4 in the 'compliant' group and 1 in the 'non-compliant' group.

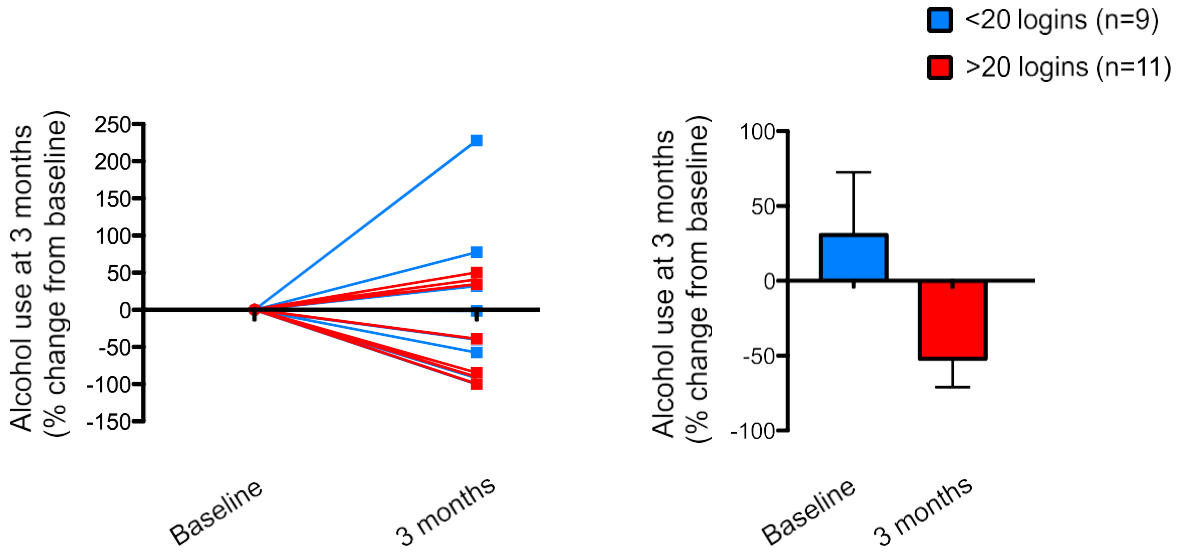

Figure 3: Change in alcohol use over study period for all participants *(left panel)*, and stratified by compliance with app *(right panel).*

Qualitative feedback was obtained through interview with a number of participants who were compliant with the app. A structured, focussed interview with one participant was video recorded, and content will be presented at the final event. Specific quotes from these interviews are presented below.

Participants used the breathalyser to monitor abstinence as well as alcohol use. A number of participants reported that having an objective, demonstrable confirmation of abstinence was empowering.

- "*When I had the breathalyser, it did empower me. I just felt like I was in control and it was easy to use, you just plugged it in where the headphone jack is of the phone. It felt really good, to actually see and feel proud that you are sober and showing that you are sober felt really good and empowering".*

- *"This was the first chance I've had to show my mother I've been sober. She never used to believe me".*

Participants were encouraged to record cravings for alcohol, and in response to cravings, users were sent motivational messaging containing pre-designed content including pictures of family or connecting to named supportive friends or the charity helpline 'Drinkline'.

- *"So when I had a craving, I would press the button and instantly the picture would come up of my daughter and that's your reason for doing it, to stay sober, so it gives you that reason - your daughter's face coming up."*

- *"I did have a nominated friend on the app. She is part of my plan around alcoholism as well. She is the person that if I have a craving or a low day, I can look her up. So her number would come up on the app so I could easily call her and tell her the problems I'm having with the drinks. It was very useful to have on there."*

This was a pilot study, to assess the suitability of the features of the app described above, and the efficacy of the intervention. The study confirmed a large proportion of this cohort of ARLD patients remain difficult to engage with healthcare interventions. Nevertheless, in the subgroup that used the app and device, there is evidence of benefit both in terms of alcohol use and qualitative feedback. Although this study is limited by the lack of a control group, the finding of a 'dose-response' with the intervention is encouraging. This study has paved the way for a larger controlled study of this intervention in ARLD patients, in whom on-going alcohol use is a major unmet clinical need.

Part 3: Cost impact

At present, the services provided by the Alcohol Care Team are paid for indirectly or directly by local commissioning groups. Since reducing hospital admissions due to alcohol will lead to decreased revenue for the Trust, the best way to fund an app such as AlcoChange would be to negotiate a QIPP with local commissioning groups with the aim of decreasing alcohol consumption and consequently alcohol-related hospital admissions.

Royal Free London (RFL) has 1100 alcohol-related admissions per year. Of these, 40% of patients are re-admitted within 12 months. Thus, if we focus on re-admissions alone, with an average inpatient stay of 5 days and inpatient stay £400/day, the bed-stay cost of alcohol-related readmissions at RFL is £880,000.

Of the 1100 alcohol-related admissions, only about 40% are referred to the Alcohol Care Team. From our data, we estimate that 50% have a smart phone, of whom 70% are smartphone literate. Thus, we have approximately 150 suitable patients at Royal Free London per year.

The cost of the breathalyser, app and hosting of the secure server is £120 per

patient, amounting to an outlay of £18,000 for 150 patients. Extrapolating our pilot data, we can assume that 50% of suitable patients will comply with the app and reduce their alcohol consumption by 50%, leading to a linear reduction in alcohol-related harm and hospital admissions. Thus, a 50% reduction in readmissions amongst the 75 patients using AlcoChange, leads to a saving of £30,000/year. This is excluding any of the routine investigation or management costs of these patients.

Further, for every patient admitted directly with an alcohol-related admission, there are 3 other admissions indirectly related. Since AlcoChange is an easily scalable intervention, there is the potential to screen and treat a greater proportion of alcohol-related admissions, leading to greater savings than listed above. Therefore, this intervention would reduce primary alcohol-related admissions as well as readmissions. There would also be savings in terms of alcohol liaison nurse time.

Since this cost saving is a direct result of decreased alcohol consumption, costs are unlikely to be transferred to other sector. There are also potential wider effects in terms of reducing community-level alcohol related harm.

Part 4: Learning from your project

This project was initiated with the aim of developing a smartphone intervention for the maintenance of abstinence in patients with ARLD. Since on-going alcohol use is the most important factor determining survival in patients with ARLD, and there are currently no effective pharmacological therapies, our goal was to determine if a smartphone tool could provide a scalable intervention for these high-risk patients.

Our intention was for this project to act as a pilot study, to determine acceptability of the app/device, and also to provide early data to influence key opinion leaders to consider this intervention in the design of definitive clinical trials which will take place in the next 3-5 years. Since the alcohol field is high on the public health agenda (eg James Lind Alliance), and definitive clinical trials and guidance are currently being drafted, we considered acceptance of a smartphone intervention by the alcohol field an appropriate milestone for this project. Our data has been reviewed by the BSG-NIHR Alcohol Clinical Trials group, who are currently considering the design of a large clinical trial for alcohol use disorder in ARLD. We also plan to present our data to local commissioners, and have already had interest from Hackney, Slough and Blackpool CCGs.

Several members of the wider 'team' had input into the design of the app and the project. The app was designed Kevin Moore and myself, with input from local alcohol service users at a focus group, and specialists in alcohol use disorders such as Prof Colin Drummond. The major workload of this project was the screening and recruitment of eligible participants. This was conducted by myself, along with clinical fellows and nurses working as part of the NIHR clinical trials facility at RFL. We elected to invest some resource into these clinical fellows, rather than employing a dedicated nurse as outlined in our original application, as this gave us flexibility in the duration of our recruitment period. This was particularly important in view of the delay in commencing the study (see below).

The major challenges in the progress of this project were: (i) the delay in initiation of the study due to problems with ethical approval, and (ii) the lack of smartphone use amongst the ARLD patient population. Both of these limitations are discussed below.

We chose to obtain ethical approval prior to commencing this study, since this would increase the 'credibility' of the project, allow the findings to be published in a peer-reviewed journal and thereby improve the dissemination and spread of the project. A major hurdle was obtaining this ethical approval, since local ethics committee were unfamiliar with 'app' based studies and there was discussion as to whether this represented a new 'medical device', which would require much greater regulation. There was considerable learning around this point, as our project coincided with MHRA guidance on the topic. Specifically, our app and breathalyser was CE marked and MHRA approved as an *in vitro diagnostic device*, rather than a medical device. However, the local ethics committees were unfamiliar with the updated guidance and

this designation, thereby causing delays to the start of our project. Once this hurdle had been overcome, we distilled the learning from this process as a report to the Health Foundation as a ‘users guide’ for other teams designing healthcare apps (appendix 1c).

The other major barrier to progress with this project was the use of smartphones within the population with ARLD. We did anticipate this possibility – we estimated 65% smartphone penetrance in our original application to the Health Foundation. However, as noted in figure 2a the actual figure is lower at 50%. Moreover, a number of these individuals were not necessarily smartphone ‘literate’, and despite owning a smartphone do not engage with apps or devices. Nevertheless, this limitation is likely to change over the coming years as smartphone penetrance increases. Our view was that the pilot data suggested that there was a ‘sweet spot’ of individuals that owned a smartphone, engaged with the app and were potentially responsive to using the app/device. This data is of value, since the smartphone literate population is likely to rise over the coming years, and any intervention that reduces alcohol consumption in the high-risk ARLD population will lead to decreases in morbidity, mortality and associated healthcare costs.

Part 5: Sustainability and spread

This project will not be sustained in its current form beyond the funding period. The pilot study has already been extended to allow collection of sufficient data to meet our target of 60 participants. The rationale for this is to collect data from a sufficiently powered cohort to have statistically valid results, and to facilitate publication of our findings in a peer-reviewed journal.

The area of alcohol-related harm is currently of considerable public health interest. The national guidelines for alcohol use were revised by the CMOs in 2016, and the recent Lancet Commission into Liver Disease has gained considerable political traction in addressing the primary and secondary prevention of liver disease. As such, we believe there is an opportunity to influence research and clinical practice policy at a high level, if we can generate rigorous, high-quality data.

In line with this strategy, and as noted previously, our initial data has been presented to the BSG-NIHR Alcohol Clinical Trials group. This is a significant opportunity for our intervention to be included in the design of a large clinical trial of interventions for alcohol use order, which is likely to shape clinical practice for a number of years. To maximise this opportunity, our goal has been to complete the recruitment of our pilot cohort, and submit our findings for peer-reviewed publication, in time to influence the design of this proposed large trial (over the coming 6-8 months).

The project has received significant media attention over the last 18 months. Specifically, AlcoChange has been covered by the Evening Standard, Newsweek magazine, and will also be featured in an upcoming Channel 4 documentary on alcohol misuse. All of this coverage has helped to gather interest in the project from local stakeholders such as alcohol workers, commissioners, charities and patients.

Through these networks, and existing primary and secondary care networks, we have developed contacts with interested parties in Hackney, Slough and Blackpool CCGs. As outlined previously, our intention is to negotiate a QIPP model with the aim of decreasing alcohol use, whereby the costs are frontloaded by the CCGs to enable to intervention to be set up. Since the app/device is an easily scalable intervention, we envisage that this model could be used to replicate the project at other sites including the above CCGs.

We believe that the biggest opportunity for embedding and spreading this innovation is through publication in a peer-reviewed journal, and subsequent dissemination of our findings. This will facilitate possible inclusion of AlcoChange in upcoming large-scale clinical trials, as well as help to engage CCGs to consider QIPP models for AlcoChange to be introduced at other clinical sites. Therefore, the major upcoming milestone for this project is completion of recruitment and publication. The resources to facilitate this are already in place, and we anticipate completion within 6-8 months.

Appendix 1: Resources and appendices

Appendix 1 - Media Coverage of AlcoChange:

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New app to help patients quit alcohol

12 June 2015

A team at the Royal Free Hospital has been awarded funding from the Health Foundation for a mobile app, AlcoChange, which aims to help patients cut down on alcohol.

Liver specialists Dr Gautam Mehta, Professor Rajiv Jalan and Professor Kevin Moore, have been awarded £75,000 from the Health Foundation, a healthcare charity. The money will be used to provide the app, as well as a breathalyser that plugs into the smartphone, to patients with alcoholic liver disease to help them drink within safe limits.

As part of a 15-month pilot, 60 patients with ALD will use the AlcoChange app to monitor their drinking habits and help them cut down on alcohol. The app works by using personal data to establish the most effective times to send patients messages reminding them not to drink. In addition, the app gathers information about the patients' drinking habits, which is then fed back to clinical staff at the Royal Free Hospital. This allows staff to closely monitor whether patients are drinking too much and, where necessary, provide them with additional support to cut down on alcohol. AlcoChange helps patients set achievable goals to reduce the amount they drink, and monitor their alcohol use through the smartphone breathalyser.

Dr Gautam Mehta said: "I'm thrilled to have been awarded this money by the Health Foundation. It will go a long way to helping patients reduce their alcohol intake.

Newsweek

TECH & SCIENCE

ALCOHOLICS TEST SMARTPHONE APP THAT WARNS OF NEARBY DRINKING VENUES

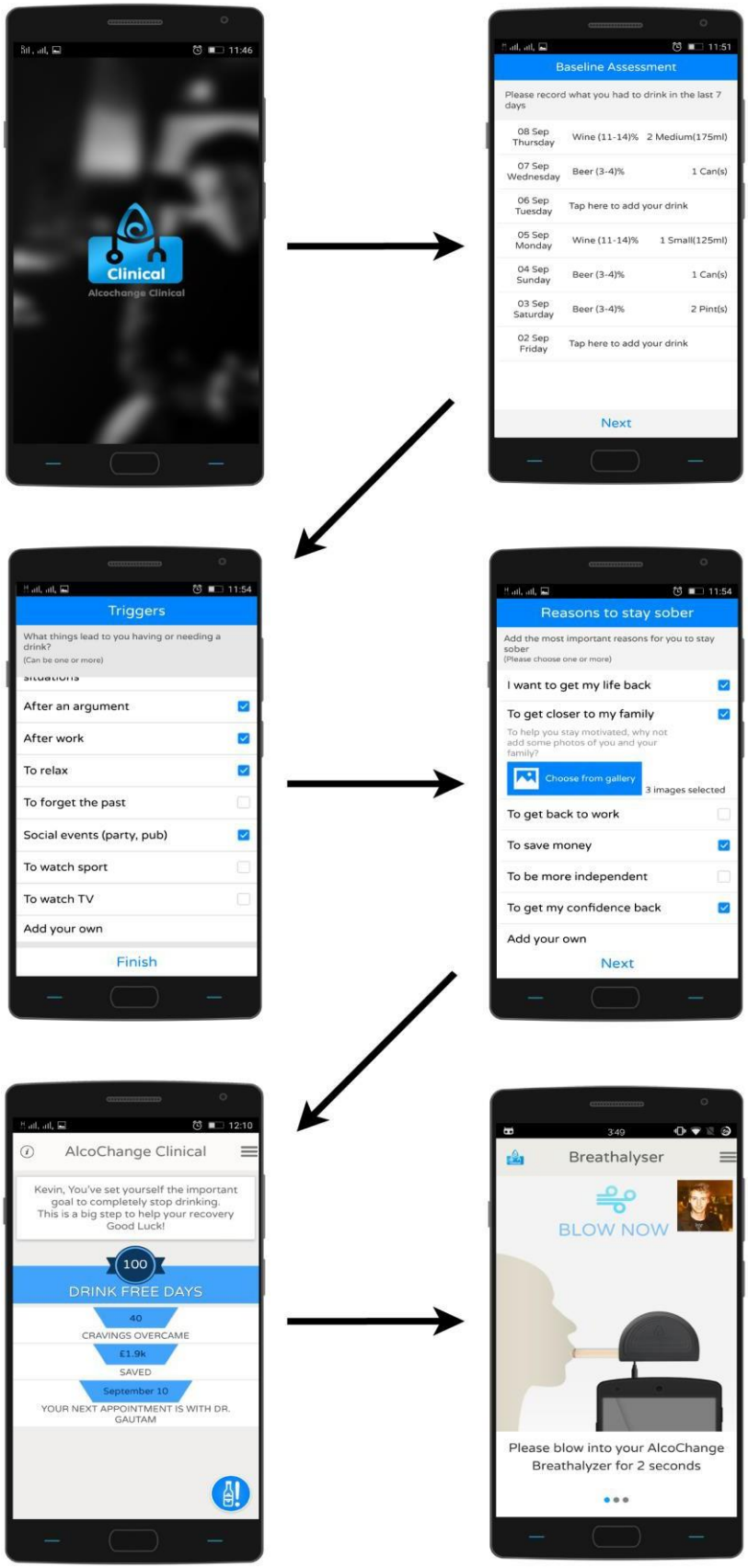
BY ELISABETH PERLMAN ON 6/16/15 AT 8:36 AM

EveningStandard

AlcoChange: The new app aimed at keeping heavy drinkers out of the pub

A smartphone app that "nudges" patients with alcohol-related liver disease away from their favourite drinking dens and off-licences is being trialled by a London hospital.

Appendix 1b - Screenshots of App Flow:



Appendix 1c - EU and MHRA Guidance on Mobile Health Apps:

Existing European Union (EU) guidance on mobile apps and devices is covered by the Medical Devices Directive MDD93/42/EEC, the Active Implantable Directive AIMDD90/385/EEC, and the In Vitro Diagnostics Directive IVD98/79/EC. This regulatory framework dates from 2012, and, in general, comments on 'active medical devices', as well as 'stand alone software' including software for data collection, symptom monitoring and decision-support software. The EU guidance is not legally binding, but is widely adopted by the MHRA. A copy of the guidance notes for these regulations (MEDDEV 2.1/6) is attached to this document.

However, this guidance pre-dates the proliferation in mobile apps focussed on lifestyle monitoring and 'behaviour-change'. There was general recognition that further guidance was required to cover the healthcare applications of the 'mHealth' field, and the European Comission (EC) published a Green Paper on mHealth in April 2014, which launched a public consultation on mHealth in the EU, and also prompted a review of existing EU regulation for mHealth interventions that fall under the classification of a medical device. This revision of the Medical Device Directive is currently underway, and the recommendations are proposed to come into effect "gradually from 2015 to 2019". Details of the revision process are available here: http://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework/revision/index_en.htm

Essentially, the revisions focus on standalone software that has a 'medical purpose', intended for the purposes of: (a) diagnosis, prevention, monitoring, treatment or alleviation of disease; (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; (c) investigation, replacement or modification of the anatomy or of a physiological process; or (d) control of conception.

These distinctions have relevance for mobile apps which have a role in the prevention and self-monitoring of disease. The distinction seems to relate to whether the app is playing a role in the primary prevention, or secondary prevention of disease. For example, a diet/exercise tracker may be a 'wellness' app for a healthy individual, but in the context of type 2 diabetes becomes a disease-monitoring app, which may fall under the new Medical Devices Directive. Similarly, the context of use may affect classification. The MHRA guidance (also attached) uses the example of an app with an accelerometer that acts as a falls detector. If used for epileptic patients, this would qualify as a medical device, but if used for detecting whether an elderly person has got up from a chair in a social care context, it may classify as wellness. This distinction will be key to the regulatory landscape of mHealth apps as the EU guidance is gradually introduced over the next 5 years.

Some of the complex issues regarding mHealth apps have begun to be recognised by the NHS – the online NHS Health Apps Library has a review process to ensure that apps have compliance with data protection rules. However, this process does not currently involve a step assessing whether the EU MDD regulations apply in a particular case.

The major issue affecting new mHealth interventions in the UK, some of which may

be supported by the Health Foundation, is whether the intervention will be classified as a medical device under the new EU regulation which are likely to be adopted by the MHRA. Thus, whilst these interventions may be supported and used currently, their adoption in a disease-management setting may not be possible after new EU guidance is ratified.

With regard to the AlcoChange device, this has already been registered as an in vitro diagnostic device under existing EU regulation IVD98/79/EC, and has a CE mark which is equivalent to MHRA approval. As such, the AlcoChange app and device will be compliant with any prospective EU regulations. It's worth adding at this point, that this is a serendipitous situation, related entirely to the fact that AlcoChange consists of an app and an in vitro device, and would therefore require CE/MHRA approval regardless of the EU regulatory landscape. However, as mentioned above, any healthcare apps that are involved in disease management including self-monitoring or behaviour-change are likely to require MHRA approval over the coming years.