EFAR-FVG: Effectiveness of primary care based facilitated access to alcohol reduction website – a randomised controlled non-inferiority trial in Region Friuli Venezia Giulia, IT

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Title

EFAR-FVG: Effectiveness of primary care based facilitated access to alcohol reduction website – a randomised controlled non-inferiority trial in Region Friuli Venezia Giulia, IT.

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Authors' contributions
PS and PW are the principal investigators, designed the study and drafted the article
ES, RM, HL, RD, LV, CT; have made substantial contributions to conception and design of the project
NF has been involved in drafting the manuscript or revising it critically for important intellectual content;
LC and GT: have given final approval of the version to be published

Key word: alcohol, risky drinking, Internet, primary care, brief intervention.

Word count: 3051

Abstract

Introduction

Facilitated access to an alcohol reduction website could offer primary care professionals an attractive and time-saving alternative to face to face intervention, but there is currently limited evidence about its effectiveness.

Objectives

To test the effectiveness in primary care of facilitated access care to an alcohol reduction website for risky drinkers compared to face-to-face brief intervention.

Methods

Randomised controlled non-inferiority trial for risky drinkers comparing facilitated access to a dedicated website with face to face brief intervention in general practices. Patients screening positive will be randomised to face to face intervention or facilitated access. The trial will be conducted in 3 phases: set-up (website development, beta testing and GP training), pilot study and main trial.

Ethics: The protocolx was approved by the ethical committee on march 2012.

Trial registration: www.Clinicaltrials.gov: NCT01638338

Article Summary –

Article focus

- Is Web-site facilitated acces to alcohol Brief Intervention as good as face to face BI?
- Is primary care the right setting to promote internet?

Key messages

- Risky drinking is an iportant health issue
- General practices are too busy to provide BI on alcohol

Strenghts and limitations

- A new wide spread tool is proposed to reduce risky drinking
- If not effective, this study promotes BI among GPs
- The domestic use of computers is not widespread in Italy and community involvement might be important

Background

Hazardous alcohol consumption is a significant public health problem, with an estimated 3.8% of all global deaths and 4.6% of global disability-adjusted life years lost attributable to alcohol.[1] The European Union (EU) is the heaviest drinking region of the world, drinking an average of 11 litres of pure alcohol per adult each year.[2] In Region Friuli Venezia Giulia risky alcohol consumption varies between the 23,2 and the 37,4% of the general population, being more significant in young adults (18-24 yrs./old).[3-6] There is strong evidence that screening and brief interventions (SBIs) are effective in reducing both alcohol consumption and the harms associated with hazardous drinking.[7] However, in primary care, less than 10% of hazardous and harmful drinkers are identified and less than 5% of those who could benefit are offered brief interventions.[8] One of the principal reasons for this is that conventional delivery of brief

intervention can add up to 15 minutes to the primary consultation. In Italy, research on the topic of SBI in general practice is scarce and although there is some evidence about GPs' knowledge and attitudes,[9] no evidence exists on the extent to which SBI's are currently implemented.

The provision of facilitated access to an alcohol reduction website could significantly increase brief intervention rates by offering primary care professionals an attractive time-saving alternative to face to face intervention. A review of trials of computer based interventions in college drinkers found them to be more effective than no treatment and as effective as alternative treatment approaches. The recent online trial of Down Your Drink (DYD - http://www.downyourdrink.org.uk/) indicated potentially significant reductions in alcohol consumption and risky drinking behaviours in subjects who used the trial websites,[10] and a number of initiatives are underway to test the acceptability of this approach.[11] The EU-funded ODHIN trial currently underway in 5 European countries is designed to determine the impact of facilitated access on levels of implementation of brief interventions by primary care practitioners. The DYD website has also been deployed in two NHS Primary Care Trust settings in London, including automated baseline assessment of alcohol consumption and alcohol related problems together with facilitated access by primary care professionals. The initial findings suggested that facilitated access is both feasible and attractive in these primary care settings, but as yet there is no published evidence about effectiveness.

The EFAR-FVG trial will seek evidence of equivalence in patient outcomes of facilitated access to an alcohol reduction website compared with conventional face to face brief intervention, and will additionally provide data about cost effectiveness. The trial will be implemented in the Region Friuli Venezia Giulia, Italy and will test the hypothesis that brief intervention for risky

drinkers delivered in primary care through facilitated access to an alcohol reduction website will reduce hazardous drinking as much or more than to face to face brief intervention by GPs

METHODS/DESIGN

1: Trial design: With the exception of the face-to-face intervention, all elements of the trial from recruitment to follow-up be conducted online using a tried and tested methodology employed by the UK-based research team in a large-scale online trial of the website www.downyourdrink.org.uk. The intervention condition will consist of online GP-facilitated access to an internet based brief intervention for risky dinking (see below). The comparison condition will consist of face to face brief intervention performed by general practitioners. A health economic evaluation will be undertaken in order to enable the calculation of cost effectiveness.

2: Setting and practice eligibility: The trial will be run in general practices in the Region of Friuli Venezia Giulia. A sample of practices will be invited by email and letter to participate in the study. Practices expressing an interest in the trial and a willingness to actively distribute a website brochure will be considered for inclusion in the study. Preference will be given to respondents with at least 1000 registered patients and a practice nurse and/or receptionist. Those selected for the trial will be required to undergo training (see page 13: Practice Training). Payments will be made to practices as appropriate to incentivise the distribution of trial brochures, the delivery of face-to-face intervention and the active follow-up of non-responders. In the municipalities of the participating practices, contact will be made with the local authorities to explore the possibility to utilize libraries or social centre as internet access sites for patients who do not have such facilities at home or at work. Information will also be given to the public with local newsletters or conferences.

3: Patient eligibility: All patients aged 16 or over who attend the participating practices during the study period will be eligible to receive a trial brochure. Over 80s, people suffering from severe psychiatric disorder, vision impaired, terminally ill or immigrants with poor command of the Italian language will be excluded from the study.

4: Screening:

A: Distribution of the website brochure: For the duration of the trial, a nominated GP or another staff member in each participating practice will distribute website brochures to all eligible patients. These will describe the website, set out the URL, and invite the patient to login for an alcohol screening test using the unique login number printed on their brochure. The number will comprise the practice identifier (first 3 digits) and a randomly generated patient identifier (last 4 digits); only patients using these numbers will be eligible for the trial (See Appendix). The GP or other staff member will offer all eligible patients a website brochure, accompanied by strong verbal encouragement to login. Patients will also be asked whether they have adequate access to online facilities at home and/or at work, and information will be given as appropriate about additional internet access facilities in their locality. Accurate records will be kept matching each patient's unique login number to their practice patient identifier; these records will be kept highly secure in compliance with practice policies and the relevant EU regulations. Patients who decide not make use of the facility will be invited to inform their GP of their decision by completing and returning a simple tear-off section on the brochure.

B: The online screening module: Following login to the EFAR FVG DYD website, patients will be invited to access the interactive part of the site containing the screening module for risky drinking. This comprises the 3-question short Alcohol Use Disorders Identification Test AUDIT-C , the Italian version of which has been validated,[12] and a brief online consent form asking for agreement to the result of the screening test to be sent to the GP practice and recorded in the

electronic health care record. For the purposes of the trial, AUDIT-C score cut points of 4 for women and 5 for men will be adopted for case definition. Patients screening negative will receive a standard message from their GP advising that that their responses indicate that their stated drinking patterns fall within the guidelines for sensible drinking; they will receive no further request to provide information. Those scoring positive will receive a personalised message from their GP advising that their stated drinking patterns indicate that they are at risk from their drinking and inviting them to take part in the EFAR FVG study (see Appendix: EFAR FVG DYD website).

5: Consent: Those screening positive for risky drinking on the AUDIT-C and confirming that they do not suffer from severe psychiatric disorder or a terminal illness will be invited to complete an online consent module, providing information about the trial and what will be requested of them as participants. Those providing consent will be invited to complete the baseline assessment.

6: Baseline assessment: Patients providing consent will be asked to complete a set of baseline assessment questionnaires including the following:

1) The 10 question Alcohol Use Disorders Identification Test (AUDIT)[13] validated Italian version
2) The EQ-5D[14] quality of life questionnaire, validated Italian version

7: Randomization: Those completing the baseline questionnaires will undergo automated online randomization into two arms:

A: Intervention group: Facilitated access to the alcohol reduction website: Those in the intervention group will be taken to the introductory page containing a personalised online message from their GP with tailored feedback about their responses to the alcohol questionnaires and personalised encouragement to proceed to access the online brief

intervention package (see Appendix: EFAR FVG DYD website). Patients will encouraged to spend at least 15 minutes on the site in the first instance, and will receive an email 1 week later encouraging them to login again. They will be asked to review their alcohol consumption and encouraged to discuss their website experience when they next see their GP.

B: Comparison group: ace to face brief intervention by the GP:

Patients allocated to the comparison group will be invited to check a box online which will automatically generate an email to their practice requesting a GP appointment for a face to face brief intervention within the next 7-10 days. At the appointment, the patient will receive an intervention be based on the brief motivational interview:[15]

1. **A**ssessment of the motivation to change the risky behaviour
2. **A**ssessment of the Stage of Change
3. **A**dvice - explicit advice on changing drinking behaviour
4. **E**mpathy - role of counsellor important
5. **C**apacity building - instilling optimism that goals achievable

Non attenders will be offered up to 3 additional appointments in order to optimise intervention rates.

8: Follow up: Follow up will take place at 1m and 3m after randomisation in the pilot phase, and at 3m, 6m and 12m in the main trial. The assessment will consist of the following:

1) The 10 question Alcohol Use Disorders Identification Test (AUDIT) validated Italian version
2) The EQ-5D quality of life questionnaire, validated Italian version

Every effort will be made to secure the highest possible response rates. In the first instance, each patient in the trial will receive an automated email requesting them to login and complete the assessment questionnaires. Failure to do so will result in further emails at 1 week and 2

week intervals. Persistent failure will be notified to the patient's GP who will contact them by letter, phone or in person in order to ensure that their assessment is completed.

9: Data management and security: Data files generated by the online packages in each of the trial settings will be stored securely on servers according to privacy. The only identifiers will be the unique login number. The files generated by the practices linking the unique login numbers to the patient identifiers will be will be stored securely along with other clinical data in the practice. Regular checks of the quality of the data will be carried out under the supervision of the research team.

10: Practice training: Staff in the participating practices will be required to undertake at least one training session in which they will be presented with information about the design of the trial, the website brochure and the EFAR FVG DYD website. The GPs will be presented with the options relating to tailoring of the personalised multi-media online message, and will be given training in the use of face to face brief intervention (see Appendix). All participating GPs will be required to familiarise themselves with the website and to satisfy appropriate standards for the delivery of brief intervention.

11: Statistical analysis: The principal outcome measure will be the proportion of risky drinkers as classified by responses to the AUDIT-10 question scale at 3 months following randomisation. In order to assess non-inferiority of facilitated access compared with face-to-face brief intervention, the proportions of risky drinkers in each group will be computed. Facilitated access will be deemed not inferior to face-to-face treatment at a one sided alpha of 2.5 % if the difference between the proportions of risky drinkers in the facilitated access group and the face-to-face brief intervention group is below a specified margin of non-inferiority of 10%. Assuming a reduction of 30% in the proportion of risky drinkers in the face-to-face intervention group and

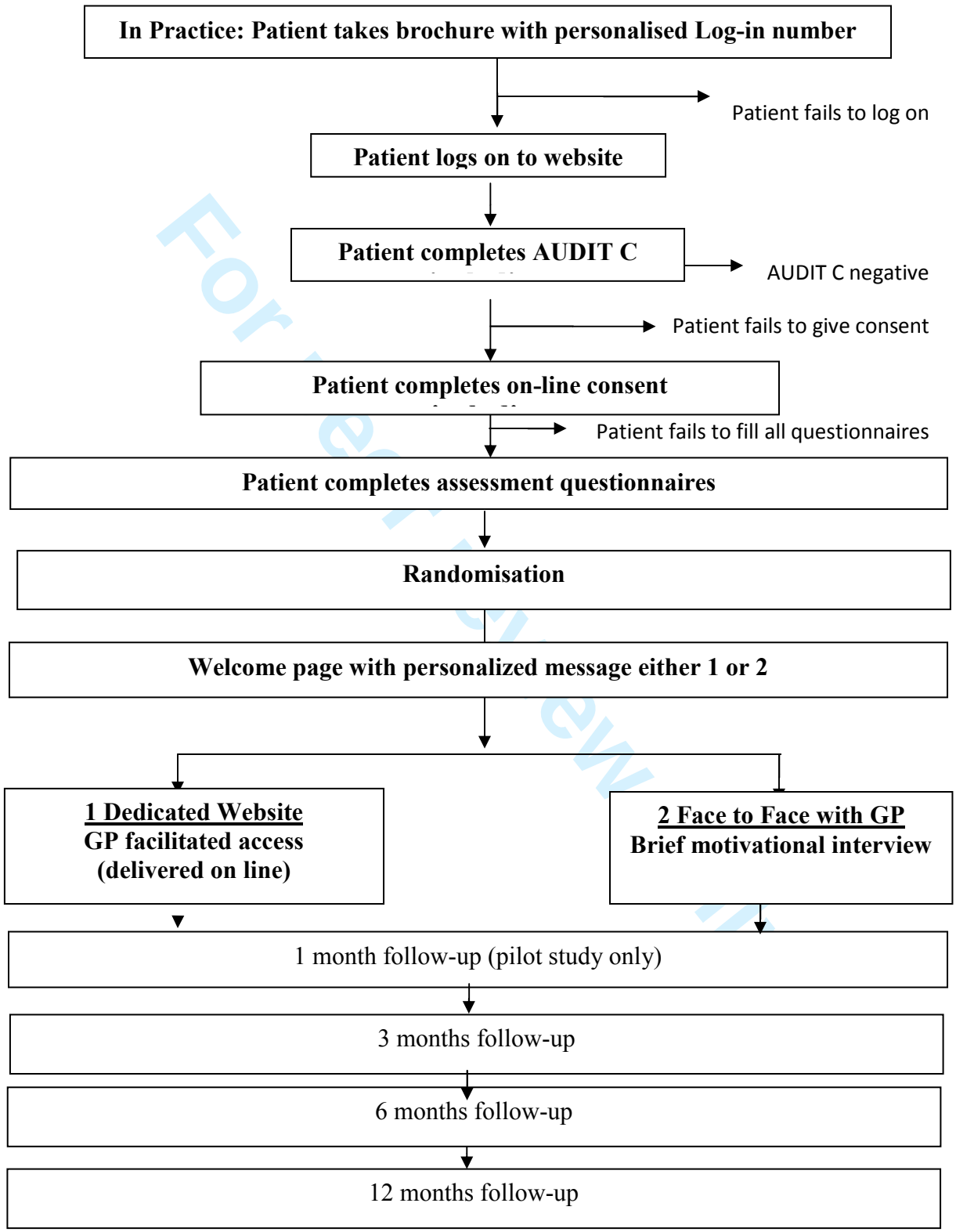
allowing for overall attrition of 10% of patients in the trial, it is calculated that 500 patients will be required in each group to give the trial 90% power (1-beta) to reject the null hypothesis that facilitated access is inferior to face-to face intervention.

11: Health economics:

Analysis will be performed to determine the cost-effectiveness of patients receiving online intervention compared to conventional face-to-face brief intervention by the GPs. Cost-effectiveness will be calculated as cost per quality adjusted life year (QALY) gained using the EQ-5D. Health care costs will include the costs of screening, GP contact including face-to-face brief intervention, staff training, website upkeep and, where possible, alcohol-related health care contacts.

12: Ethical approval, research governance and data access**.** Ethical approval will be sought in as appropriate.

Figure 1: EFAR FRIULI: PATIENT FLOW CHART



Appendix 1:

Development and implementation of the EFAR-FVG DownYourDrink (EFAR FVG DYD) website

General: The EFAR-FVG DownYourDrink (EFAR FVG DYD) website: EFAR FVG DYD is an Italian language on-line facility, which includes the screening, consent, assessment, randomisation and follow-up modules necessary for the conduct of the trial, as well as the online intervention for the patients in the intervention group. The site has been developed from the www.DownYourDrink.org.uk (DYD) website developed for the DYD-RCT trial (Wallace et al 2011) and adapted for use in the context of the Region of Friuli Venezia Giulia (see "Appendix 1: Website development" below). Details of the DYD website and the psychological theory which has underpinned its development have been reported elsewhere (Linke et al, 2009). General access is available to the EFAR FVG DYD website through the Region Friuli VG official web site and other national web pages to be identified with the Istituto Superiore della Sanità in Rome. Entry to the trial is restricted to those who have been given a trial-specific log in number. The Regional portal offers general advice about different aspects of healthy lifestyle, and gives specific encouragement to the visitor to complete the AUDIT-C screening module for risky drinking (see "Screening" below). The website calculates the respondents' AUDIT C scores. For respondents who screen negative, a message is generated advising that that their responses indicate that their stated drinking patterns fall within the guidelines for sensible drinking. The website routes respondents who score positive but do not have a trial-specific log in number directly to the alcohol reduction website, while those who have a trial-specific log on number are automatically provided with access to the EFAR FVG trial consent module, and subsequently to the on-line baseline assessment and thence to randomisation. The website also includes a facility to deliver a personalised multi-media (written/audio/video) message from the patient's GP, identified by the respondent's unique log-in number. The programme has a facility enabling

the message to be tailored to reflect each GP's preferences about the use of multimedia to deliver their personalised message. It also automatically generates different messages depending on the patient's randomisation status and produces periodic automatic messages to respondents in the intervention group reminding them to re-visit the site. The website generated feedback to each participating GP on their recruitment figures relative to the other GP trialists. Finally, it generates automatic emails to elicit completion of the follow-up questionnaires at the selected time intervals from the point of randomisation.

Website development: The first stage will be to adapt the UK-based DYD website for use as a GP online facilitated internet-based brief intervention. DYD is an evidence-based intervention, incorporating tailored feedback, cognitive behavioural therapy and motivational interviewing.[16] It has been extensively evaluated, most recently through a large scale on-line trial involving nearly 8000 subjects.[10] EFAR will be informed by developments that underpinned the online trial of DYD, including on-line recruitment, consent, assessment, randomisation, intervention and follow-up. Country-specific information such as recommended guidelines for alcohol intake, definitions of standard drinks and alcohol-related laws will be included. The screening and self assessment questionnaires will be incorporated for on-line administration, as will standardised data management tools and content management systems.

Tailoring and online GP-facilitation: Possibility will be given to each participating practice to create a tailored version of the website modified to reflect their organisational and personal identity. A menu-driven facility will enable generation of a personalised GP welcome page, incorporating one or more photographs and a written/recorded message from the GP. The tailoring and online GP-facilitation facilities will be informed by the results of beta testing in the EFAR study and the subsequent feasibility and pilot study which will involve 15 practices. GPs

with receptionist or nurse service will be chosen from a list of GP that expressed an interest on research.

Beta testing**:** Beta testing is a critical phase of developing a successful website before it goes live. It includes load testing, failure recovery, security, and platform and browser compatibility, which will occur in each of the 15 practices, and respective patients. Participants will be asked to give their online consent, work through the website and write down any feedback or suggestions they have to improve the site in terms of functionality, and/or any problems they encounter. Each participant will then partake in a short interview with a member of the research team to relay their findings. All interviews and focus groups will occur in an open-ended fashion and participants will be encouraged to provide comments, feedback and their recommended changes for the website. Where possible, participants will be reimbursed for their time and travel.

Training of the GPs**:** Identified GPs will be asked to attend a 7 hours training session. A brainstorming on Brief Interventions together with a recorded role play will be the first two hours of the training. During hour three and four the GPs will simulate face to face intervention in a video recorded Role play that will be discussed and analysed during the plenary session. The website prototype will be presented and discussed in detail, during hours five and six. The last hour of the meeting will be utilised to collect further information from the GPs with a Focus Group**.**

Creating a consensus**:** Two meetings will be held with the key stakeholders before the main trial commences in order to share the methodology and add important information. National and regional health experts will attend the meetings to provide feed-back. At the second meeting the final version of the website will be presented.

Competing interests: None

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Randomised controlled non-inferiority trial of primary care based facilitated access to an alcohol reduction website (EFAR-FVG): the study protocol

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- Is primary care the right setting to promote internet?

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- Risky drinking is an important health issue
- General practices are too busy to provide BI on alcohol

Strenghts and limitations

- A new wide spread tool is proposed to reduce risky drinking
- If not effective, this study promotes BI among GPs
- The domestic use of computers is not widespread in Italy and community involvement might be important

Revised paper January 2013

Abstract

Introduction: There is a strong body of evidence demonstrating effectiveness of brief interventions by primary care professionals for risky drinkers. However implementation levels remain low because of time constraints and other factors. Facilitated access to an alcohol reduction website offers primary care professionals a time-saving alternative to standard face to face intervention, but it is not known whether it is as effective.

Methods and analysis Randomised controlled non-inferiority trial for risky drinkers comparing facilitated access to a dedicated website with standard face to face brief intervention to be conducted in primary care settings in the Region of Friuli Giulia Venezia, Italy. Adult patients will be given a leaflet inviting them to log on to a website to complete the AUDIT-C alcohol screening questionnaire. Screen positives will be requested to complete an online trial module including consent, baseline assessment and randomisation to either standard intervention by the practitioner or facilitated access to an alcohol reduction website. Follow up assessment of risky drinking will be undertaken online at 1 month, 3 months and 1 year using the full AUDIT questionnaire. Proportions of risky drinkers in each group will be calculated and non-inferiority assessed against a specified margin of 10%. Assuming reduction of 30% of risky drinkers receiving standard intervention, 1000 patients will be required to give 90% power to reject the null hypothesis.

Ethics and dissemination: The protocol was approved by the Isontina Independent Local Ethics Committee on the 14/06/12. The findings of the trial will be disseminated through peer-reviewed journals, national and international conference presentations and public events involving the local administrations of the towns where the trial participants are resident.

Registration details: Trial registration number NCT: 01638338

Word Count : 304

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Background

Hazardous alcohol consumption is a significant public health problem, with an estimated 3.8% of all global deaths and 4.6% of global disability-adjusted life years lost attributable to alcohol.[1] The European Union (EU) is the heaviest drinking region of the world, drinking an average of 11 litres of pure alcohol per adult each year.[2] In Region Friuli Venezia Giulia risky alcohol consumption varies between the 23,2 and the 37,4% of the general population, being more significant in young adults (18-24 yrs./old).[3-6] There is strong evidence that screening and brief interventions (SBIs) are effective in reducing both alcohol consumption and the harms associated with hazardous drinking.[7] However, in primary care, less than 10% of hazardous and harmful drinkers are identified and less than 5% of those who could benefit are offered brief interventions.[8] One of the principal reasons for this is that conventional delivery of brief intervention can add up to 15 minutes to the primary consultation. In Italy, research on the topic of SBI in general practice is scarce and although there is some evidence about GPs' knowledge and attitudes,[9] no evidence exists on the extent to which SBI's are currently implemented.

The provision of facilitated access by primary care professionals to an alcohol reduction website could significantly increase brief intervention rates by offering a time-saving alternative to face to face intervention. A review of trials of computer based interventions in college drinkers found them to be more effective than no treatment and as effective as alternative treatment approaches. The recent online trial of Down Your Drink (http://www.downyourdrink.org.uk/) indicated potentially significant reductions in alcohol consumption and risky drinking behaviours in subjects who used the trial websites,[10] and a number of initiatives are underway to test the acceptability of this approach.[11] The EU-funded ODHIN trial currently underway in 5 European

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countries is designed to determine the impact of facilitated access on levels of implementation of brief interventions by primary care practitioners. The DYD website has also been deployed in two NHS Primary Care Trust settings in London, including automated baseline assessment of alcohol consumption and alcohol related problems together with facilitated access by primary care professionals. The initial findings suggest that facilitated access is both feasible and attractive in primary care settings, but evidence is required to establish whether it is as effective as standard intervention.

METHODS AND ANALYSIS

Trial design: EFAR FVG is a primary care based randomised controlled non-inferiority trial comparing facilitated access to a dedicated website for risky drinkers with standard face to face brief intervention. With the exception of the reference intervention, all components of the trial will be delivered online to patients who have been given a unique trial log-on number by their general practice. Access will be through the healthy lifestyle portal of the official website of the Region of Friuli Venezia Giulia.

The trial website: The website is an Italian language online facility which includes modules for all the key trial components including screening, consent, assessment, randomisation and follow-up. It also incorporates the alcohol reduction website for the patients in the experimental group. The site has been adapted from the www.DownYourDrink.org.uk (DYD) website developed for the DYD-RCT trial (Wallace et al 2011). Details of the DYD website and the psychological theory which has underpinned its development have been reported elsewhere (Linke et al, 2009). Country-specific information such as recommended guidelines for alcohol

intake, definitions of standard drinks and alcohol-related laws will be included. The EFAR FVG trial website will additionally incorporate a menu-driven facility to enable the GPs to personalise the automated patient messages by adding photographs of themselves and audio/video recorded messages.

Practices The trial will be conducted in primary care settings in the Italian region of Friuli Venezia Giulia, and general practices will be invited by email and letter to participate in the study. Those expressing an interest in the trial and willingness to actively distribute the brochure inviting patients to log on to the trial website will be considered for inclusion in the study. Preference will be given to practices with at least 1000 registered patients and a practice nurse and/or receptionist.

Training: All participating GPs will attend a one day training event including an overview of the EFAR FVG trial and interactive sessions on the delivery of face to face brief intervention for risky drinkers. Participants will be encouraged to familiarise themselves with the trial website and will have the opportunity to use the menu driven facility to create their own tailored patient messages.

Patient eligibility: All patients aged 18 or over who attend the participating practices during the study period will be eligible for the trial. Patients over 80 and those suffering from severe psychiatric disorder, serious visual impairment or terminal illness will be excluded from the study, as will those judged to have inadequate command of the Italian language.

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Screening: Eligible patients will be encouraged by their GP or another staff member access a specially designed healthy lifestyle website and will be given a trial brochure providing a unique access number which will enable them to log on. Once online, they will be asked to complete the 3-question short Alcohol Use Disorders Identification Test (AUDIT-C)[12] and to provide agreement to the result of the test to be sent to their practice. For the purposes of the trial, cut points of 4 for women and 5 for men will be used. Patients screening below the cut points will receive an online message advising that that their responses indicate that their stated drinking patterns fall within the guidelines for sensible drinking and will be encouraged to maintain their current drinking patterns. Those scoring at or above the cut points will receive a personalised online message from their GP advising that their stated drinking patterns indicate that they are at risk from their drinking and inviting them to take part in the study.

Consent: Screen positive subjects will be asked to complete an online form confirming that they do not meet any of the exclusion criteria and will then be invited to complete the online consent module. This provides information about the trial and what will be requested of them as participants. Those providing consent will be invited to complete the online baseline assessment.

Baseline assessment: The baseline assessment includes the following:

1: A demographic questionnaire seeking information on age, gender, level of education and occupation.

2: The 10 question Alcohol Use Disorders Identification Test (AUDIT) validated Italian version. [13]

3: D5-EQ The [quality of life questionnaire, validated Italian version [14

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Randomization: Those completing the baseline questionnaires will undergo automated online randomization.

Experimental group - facilitated access to the alcohol reduction website: Those in the experimental group will be taken to the introductory page containing a personalised online message from their GP with tailored feedback about their responses to the alcohol questionnaires. Personalised online messages from their GP will inform patients of the importance of adopting healthy drinking choices, and will encourage them to spend at least 15 minutes engaging with the alcohol reduction website in the first instance. Patients will receive an email one week later encouraging them to log on again. They will also be asked online to review their alcohol consumption and will be invited to discuss their website experience when they next see their GP.

Reference group - face to face brief intervention: Patients allocated to the standard intervention group will be invited to check a box online which will automatically generate an email to their practice requesting a GP appointment for a face to face brief intervention within the next 7-10 days. At the appointment, the patient will receive an intervention be based on the brief motivational interview:[15]

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2. **A**ssessment of the Stage of Change
3. **A**dvice - explicit advice on changing drinking behaviour
4. **E**mpathy - role of counsellor important
5. **C**apacity building - instilling optimism that goals achievable

Non-attenders will be offered up to 3 additional appointments in order to optimise intervention rates.

Follow up assessment: Follow up will take place at 1month, 3months and 12 months after randomisation and each assessment will consist of the following:

1) The 10 question Alcohol Use Disorders Identification Test (AUDIT) validated Italian version
2) D quality of life questionnaire, validated Italian version5-The EQ

Every effort will be made to optimise response rates. In the first instance, each patient in the trial will receive an automated email requesting them to login and complete the assessment questionnaires. Failure to do so will result in further emails at 1 week and 2 week intervals. Persistent failure will be notified to the patient's GP who will contact them by letter, phone or in person in order to ensure that their assessment is completed.

Statistical analysis: The principal outcome measure will be the proportion of risky drinkers as classified by responses to the AUDIT-10 question scale at 3 months following randomisation. In order to assess non-inferiority of facilitated access compared with face-to-face brief intervention, the proportions of risky drinkers in each group will be computed and compared using generalised non linear mixed models accounting for general practices as random effects. Facilitated access will be deemed not inferior to face-to-face treatment at a one sided alpha of 2.5 % if the difference between the proportions of risky drinkers in the facilitated access group and the face-to-face brief intervention group is below a specified margin of non-inferiority of

10%. Assuming a reduction of 30% in the proportion of risky drinkers in the face-to-face intervention group and allowing for overall attrition of 10% of patients in the trial, it is calculated that 500 patients will be required in each group to give the trial 90% power (1-beta) to reject the null hypothesis that facilitated access is inferior to face-to face intervention. All analyses will be described in a detailed statistical analysis plan which will be completed before unblinding and database lock.

Data management and security:

Regular checks of the quality of the data will be carried out under the supervision of the research team. Data files generated by the patients' interactions with the alcohol reduction website will be stored securely on servers in accordance with EU regulations. The only identifiers will be the unique login number. The files generated by the practices linking the unique login numbers to the patient identifiers will be will be stored securely along with other clinical data in the practice and will be accessible only to practice staff.

Ethical approval, research governance and data access.

The protocol was approved on the 14/06/12 by the Independent Local Ethics Committee for Clinical Research of the Health Services Agency N° 2 Isontina, Italy.

Funding:

This work is jointly supported by the Italian Ministry of Health and by the Regional school for the training in Primary Care of the Region Friuli-Venezia Giulia, Italy.

Authors' contributions:

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PS and PW are the principal investigators, designed the study and drafted the article. ES, RM, HL, RD, LV, CT; have made substantial contributions to conception and design of the project. NF has been involved in drafting the manuscript or revising it critically for important intellectual content. LC and GT: have given final approval of the version to be published

Competing interests:

None

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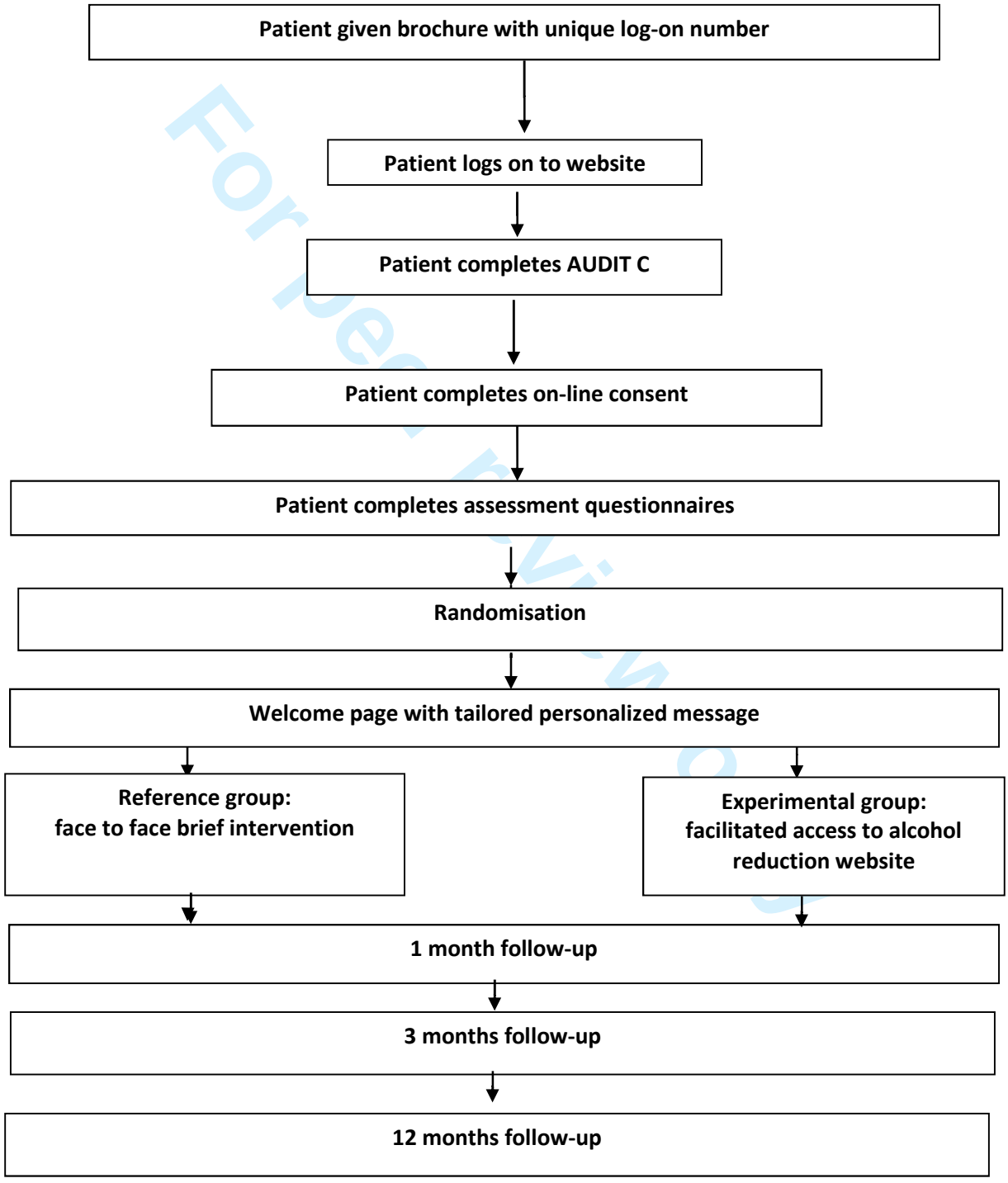
EFAR FVG TRIAL FLOW CHART



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Title: Randomised controlled non-inferiority trial of primary care based facilitated access to an alcohol reduction website (EFAR-FVG): the study protocol

Pierluigi Struzzo[1], Emanuele Scafato[2], Richard McGregor[3], Roberto Della Vedova[1], Lisa Verbano[1], Charilaos Lygidakis[4], Costanza Tersar[1], Lucia Crapesi[1], Gianni Tubaro[1], Nick Freemantle[5] and Paul Wallace.[6]

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Article Summary –

Article focus

- Is Web-site facilitated access to alcohol Brief Intervention as good as face to face BI?
- Is primary care the right setting to promote internet?

Key messages

- Risky drinking is an important health issue
- General practices are too busy to provide BI on alcohol

Strenghts and limitations

- A new wide spread tool is proposed to reduce risky drinking
- If not effective, this study promotes BI among GPs
- The domestic use of computers is not widespread in Italy and community involvement might be important

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Abstract

Introduction: There is a strong body of evidence demonstrating effectiveness of brief interventions by primary care professionals for risky drinkers. However implementation levels remain low because of time constraints and other factors. Facilitated access to an alcohol reduction website offers primary care professionals a time-saving alternative to standard face to face intervention, but it is not known whether it is as effective.

Methods and analysis Randomised controlled non-inferiority trial for risky drinkers comparing facilitated access to a dedicated website with standard face to face brief intervention to be conducted in primary care settings in the Region of Friuli Giulia Venezia, Italy. Adult patients will be given a leaflet inviting them to log on to a website to complete the AUDIT-C alcohol screening questionnaire. Screen positives will be requested to complete an online trial module including consent, baseline assessment and randomisation to either standard intervention by the practitioner or facilitated access to an alcohol reduction website. Follow up assessment of risky drinking will be undertaken online at 1 month, 3 months and 1 year using the full AUDIT questionnaire. Proportions of risky drinkers in each group will be calculated and non-inferiority assessed against a specified margin of 10%. Assuming reduction of 30% of risky drinkers receiving standard intervention, 1000 patients will be required to give 90% power to reject the null hypothesis.

Ethics and dissemination: The protocol was approved by the Isontina Independent Local Ethics Committee on the 14/06/12. The findings of the trial will be disseminated through peer-reviewed journals, national and international conference presentations and public events involving the local administrations of the towns where the trial participants are resident.

Registration details: Trial registration number NCT: 01638338

Word Count : 304

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Background

Hazardous alcohol consumption is a significant public health problem, with an estimated 3.8% of all global deaths and 4.6% of global disability-adjusted life years lost attributable to alcohol.[1] The European Union (EU) is the heaviest drinking region of the world, drinking an average of 11 litres of pure alcohol per adult each year.[2] In Region Friuli Venezia Giulia risky alcohol consumption varies between the 23,2 and the 37,4% of the general population, being more significant in young adults (18-24 yrs./old).[3-6] There is strong evidence that screening and brief interventions (SBIs) are effective in reducing both alcohol consumption and the harms associated with hazardous drinking.[7] However, in primary care, less than 10% of hazardous and harmful drinkers are identified and less than 5% of those who could benefit are offered brief interventions.[8] One of the principal reasons for this is that conventional delivery of brief intervention can add up to 15 minutes to the primary consultation. In Italy, research on the topic of SBI in general practice is scarce and although there is some evidence about GPs' knowledge and attitudes,[9] no evidence exists on the extent to which SBI's are currently implemented.

The provision of facilitated access by primary care professionals to an alcohol reduction website could significantly increase brief intervention rates by offering a time-saving alternative to face to face intervention. A review of trials of computer based interventions in college drinkers found them to be more effective than no treatment and as effective as alternative treatment approaches. The recent online trial of Down Your Drink (http://www.downyourdrink.org.uk/) indicated potentially significant reductions in alcohol consumption and risky drinking behaviours in subjects who used the trial websites,[10] and a number of initiatives are underway to test the acceptability of this approach.[11] The EU-funded ODHIN trial currently underway in 5 European

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Trial design: EFAR FVG is a primary care based randomised controlled non-inferiority trial comparing facilitated access to a dedicated website for risky drinkers with standard face to face brief intervention. With the exception of the reference intervention, all components of the trial will be delivered online to patients who have been given a unique trial log-on number by their general practice. Access will be through the healthy lifestyle portal of the official website of the Region of Friuli Venezia Giulia.

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Non-attenders will be offered up to 3 additional appointments in order to optimise intervention rates.

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Competing interests:

None

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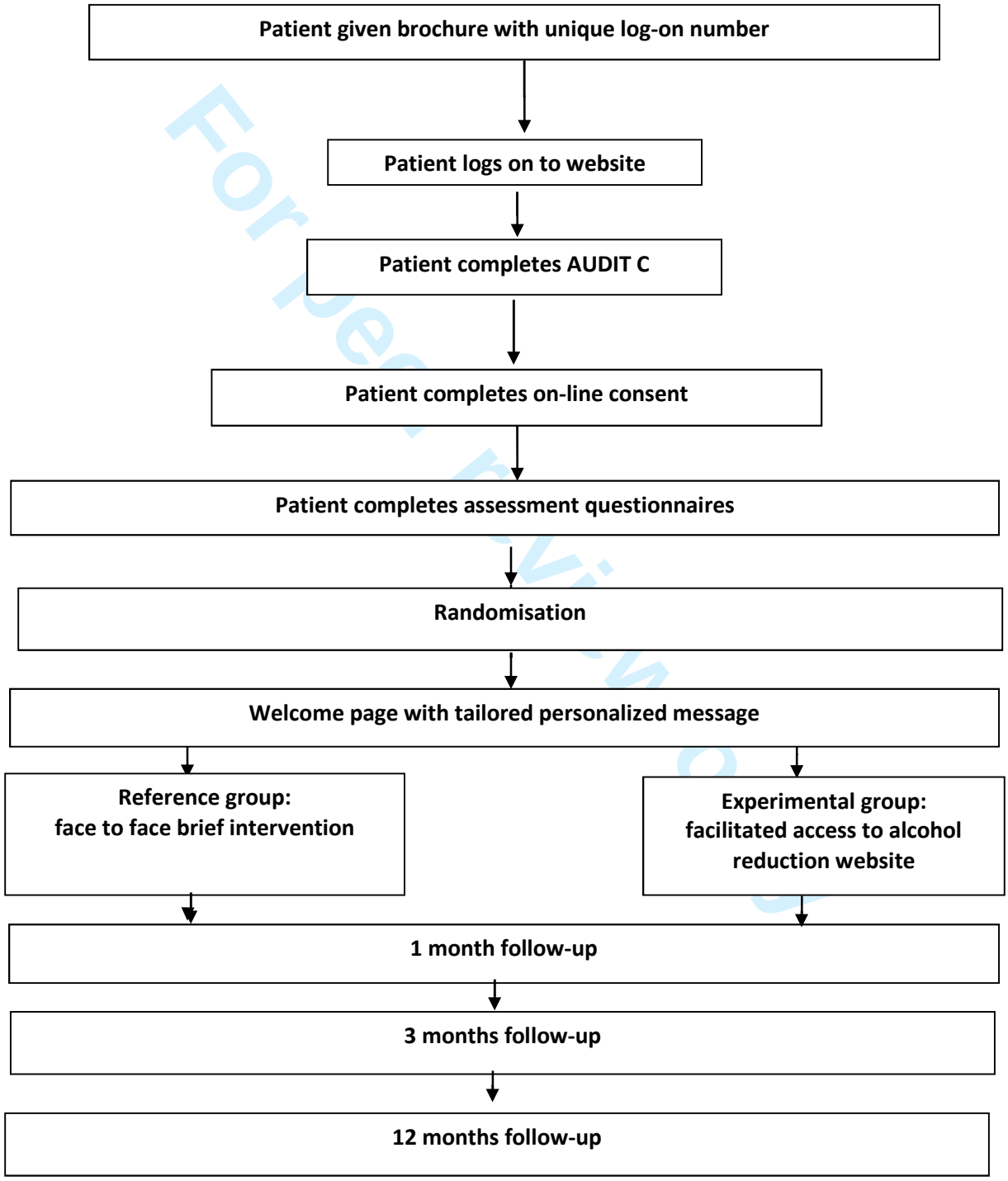
EFAR FVG TRIAL FLOW CHART



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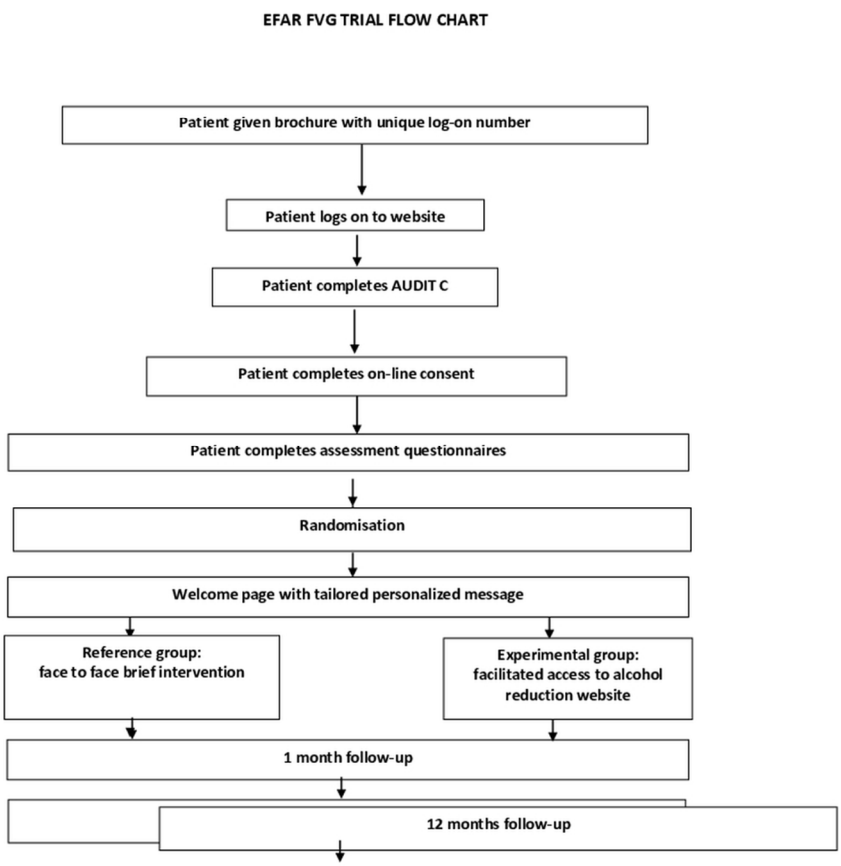

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