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Evaluation of the APUEC package: Alcohol prevention in urgent and emergency care

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Abstract

The aim of the study is to identify the current alcohol prevention practices of staff working in urgent and emergency care settings (UEC) and to explore the views of healthcare professionals and healthcare students towards the APUEC e-learning package. The study involves an online survey to determine the attitudes and views of UEC staff towards health promotion in UEC. Analysis of data from the online survey will ascertain the viability of delivering training on alcohol prevention in UEC. Through the survey, we will establish training needs of UEC staff with regards health promotion, and facilitators and barriers to implementation of prevention activity in UEC environments. We have developed online training in alcohol prevention which we will deliver to healthcare professionals and healthcare students. Using qualitative interviews, we will explore their views towards this training and best mechanisms for delivery of alcohol prevention in UEC.

Troubleshooting

Evaluation of the APUEC package: Alcohol prevention in urgent and emergency care

1

Evaluation of the APUEC package:
Alcohol prevention in urgent and emergency care
Version 1.0
18.01.22

Short title:*APUEC Study*
Sponsor: University of Nottingham
Sponsor reference:FMHS 415-1121
Funding Source: Nottingham University Hospitals Charity (UoN RIS Project 4570186: Embedding and Evaluating Health Promotion/ Illness Prevention Activity In Emergency Departments: Developing A Robust Programme Using Alcohol-Related Harm As A Proof-of Concept. This is part of the wider SCALES programme of work for which Prof.Frank Coffey is Chief Investigator).
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Study Coordinating Centre: School of Health Sciences, Queen's Medical Centre
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2 SYNOPSIS

	A	B
	Title	APUEC digital education: Alcohol prevention in urgent and emergency care
	Short title	APUEC study
	Chief Investigator	Professor Holly Blake
	Objectives	

	A	B
	Trial Configuration	Online surveyAnalysis of pre and post questions embedded within an e-learning package.Semi-structured qualitative interviews
	Setting	Community and Higher Education
	Sample size estimate	n/a (educational evaluation)
	Number of participants	Approx 500 healthcare workers or trainees completing online survey.Approx 100 healthcare workers or trainees completing APUEC training package and the embedded pre and post questions.Up to 30 interview participants.
	Eligibility criteria	Healthcare worker or trainee (online survey & evaluation)Users of the APUEC package (evaluation)
	Description of interventions	This is not an 'intervention study' but we are seeking views on an e-learning resource (available early 2022).
	Duration of study	8 months
	Randomisation and blinding	N/A
	Outcome measures	N/AOnline survey data and qualitative interview data
	Statistical methods	Survey data – descriptive analysisQualitative data will be analysed using thematic analysis.

ABBREVIATIONS

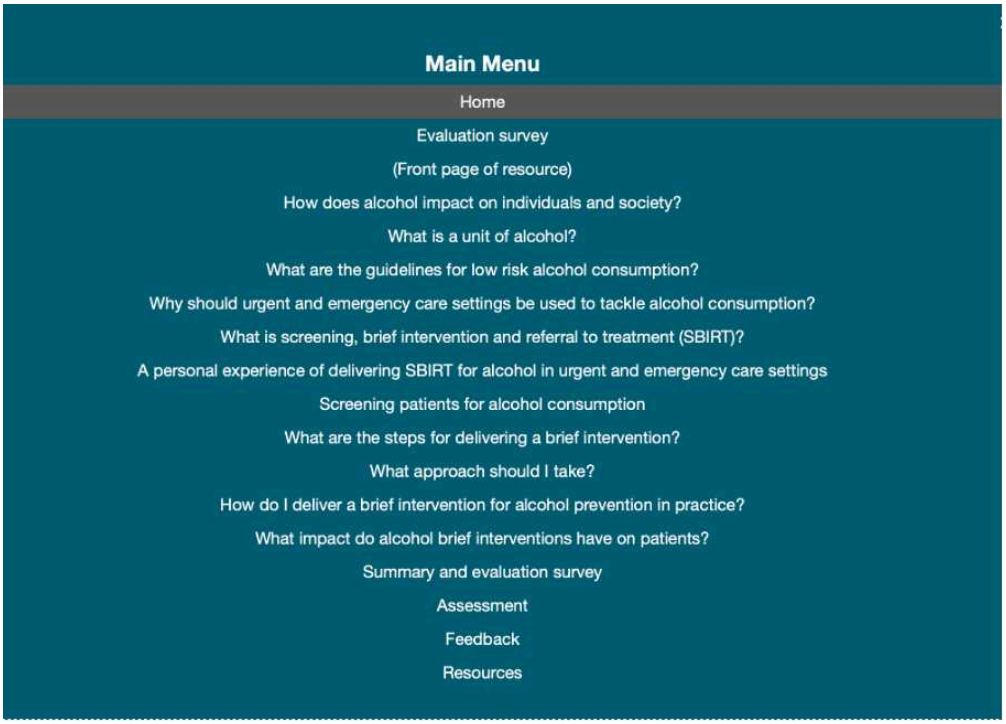
AE Adverse Event

CI Chief Investigator overall

CRF Case Report Form
DMC Data Monitoring Committee
GCP Good Clinical Practice
ICF Informed Consent Form
NHS National Health Service
PI Principal Investigator at a local centre
PIS Participant Information Sheet
REC Research Ethics Committee
R&D Research and Development department
SAE Serious Adverse Event
HWB Health and Wellbeing

Background and rationale

3 STUDY BACKGROUND INFORMATION AND RATIONALE
As part of a wider health improvement project (SCALES), we have conducted preliminary work (records analysis, staff survey and staff interviews) which is currently being written up for publication. This work suggests that emergency staff do conduct health promotion activities as part of their role (albeit in a non-structured way), many see it as part of their remit (although more research is needed on this), but staff require guidance on how to deliver brief interventions for alcohol specifically in emergency and urgent care settings. As such, we have developed an online learning resource designed to support healthcare staff with delivery of alcohol screening and brief health promotion intervention in urgent and emergency care (APUEC package, see below).
APUEC Package – summary of content



DETAILS OF PRODUCT(S)
We have developed an online learning resource designed to support healthcare staff with delivery of alcohol screening and brief health promotion intervention in urgent and emergency care. It has been developed using a rigorous methodology involving an international peer review panel of experts in health promotion, emergency care and behaviour change. It is an open access, free, online resource that will be available in early 2022.
It is designed to be relevant for healthcare staff and healthcare trainees. We are interested in knowing more about their views towards this package. This will help us to determine its value as a learning resource to support the health promotion activities in emergency departments.

Study design and objectives

4 *Educational evaluation*: involving analysis of online survey data to establish training needs, pre and post questions that are embedded within an e-learning tool, and qualitative interviews with package users.

- *Patient and Public Engagement and Involvement*(PPIE)– discussion group and email discussion with APUEC project team and members of professional networks to develop the question set for the online survey.
- *Online Survey*: to be distributed on Jisc online surveys to healthcare professionals via social media, professional networks and groups (e.g., recruited outside of the NHS). Question items will be developed through the process of PPIE and will include

attitudes to health promotion, and experience of alcohol screening / delivery of brief interventions for alcohol. This will establish training needs and help us to finalise the online package.

- *Qualitative interviews:*to be conducted with healthcare professionals and/or healthcare trainees who have used the APUEC e-learning package (recruited outside of the NHS). Interviews (using structured questionnaire and interview topic guide) will be conducted remotely by telephone or Microsoft Teams and will be audio-recorded with consent. Interviews will take place within 6 weeks of completion of APUEC and be conducted by a member of the project team (HB or trained nominee) who will receive guidance on interview approaches from the lead investigator. Interviews will be guided by semi-structured topic guide to consider the broad areas outlined above. It is expected that each interview will last approximately 30-40 minutes, although they may be shorter or longer, depending on the discussion that is generated.Digital audio equipment will be used to record the interview where possible. Recordings will be transcribed in full and anonymised. Recordings and transcriptions will be stored on a password-protected space of the University IT network. This space will be accessible only to the research team. To help encourage participation in the qualitative interviews, the study information sheet will inform participants that those who take part in an interview will be invited to opt into a prize draw to receive an Amazon voucher of £50 (optional). The prize draw winner will then be selected at random at the end of the study, using participant ID numbers, by a researcher who is not involved in recruitment or data collection.

Primary endpoint

- Analysis of survey data to explore practices, barriers and facilitators in alcohol prevention activities in urgent and emergency care settings – this will establish training needs and help us to finalise the online package.
- Analysis of pre-post survey data will allow for description of any changes in knowledge and confidence before and after using the e-learning package.
- Thematic analysis of the interview data will support the evaluation of the e-learning package - provide insight into perceptions towards the e-package and the potential for its use in healthcare settings and in academic teaching. It will help to generate recommendations for any future updates.

Study management

5 This project is led by HB who will supervise any nominees that assist with data collection (e.g., future allocation as a student project). The package itself is being developed together with a team of learning technologists. They meet at least monthly to ensure effective progress, to support data analysis, and to address any emergent issues.
The Chief Investigator has overall responsibility for the study and shall oversee all study management.
The data custodian will be the Chief Investigator.

Duration of the study and participant involvement

6 **Study Duration:**
This is an 8-month study.
We will undertake PPIE in month 1.
The online survey will be completed in month 2-3.
We will recruit APUEC package users during months 3-6 to take part in interviews, which will be completed by the end of month 7.
In month 7-8, we will transcribe and analyse data and produce a report of findings with recommendations for practice.
Participant Duration:
The PPIE activity will include a group discussion (2 hours) and email correspondence over 1 month. The online survey will take around 5-10 mins to complete.
For participants who are willing to take part in an individual interview, their participation will last approximately 30-40 minutes (end of interview).
However, all participants will be asked if they would be willing to be contacted again for future studies.
End of the Study
The end of the study will be the generation of a report with recommendations in month 8.

Selection and withdrawal of participants

7 Recruitment
Healthcare professionals and healthcare trainees will have access to this open access, online training package that will be released in early 2022. The first part of the study simply involves PPIE consultation and analysis of pre and post questions items on knowledge and confidence that are collected as part of the training package itself. As part of e-learning package educational promotion (by email, Twitter and professional networks), we will invite people to complete the APUEC training package.

This is followed by two distinct evaluation study stages:

Study Stage 1: The online survey will take place first (a separate stage of the study). A link to the online survey containing information about the survey will be sent by email to our professional networks. A copy of the final survey and study information will be forwarded to the ethics committee for records, once the PPIE stage is complete. Information gathered in the survey will help to inform the final version of (or revisions to) the APUEC package. Assumed consent will be taken for completion of the online survey.

Study Stage 2: The link to the APUEC package will be circulated to our professional networks, together with link to an online information sheet and consent form to take part

in an interview to evaluate the package. Those who provide online consent to take part in an interview will provide their contact details, and these will be used to arrange a convenient interview time, at which point the interview PIS will be attached to the booking email.

Participants for both stages will be recruited via educational mailing lists at higher education institutions, charitable and voluntary organisations, social media, professional networks and regular mailings and publications (e.g., we will recruit participants outside of NHS organisations).

Those who choose to access the e-learning package and complete an online interview consent form will be contacted by the project researcher (and will have the option to contact the project researcher themselves) to arrange an interview. All e-learning package users expressing interest in being interviewed will be able to view a participant information sheet prior to obtaining informed consent online. Interested individuals will also be able to contact a member of the project team for further information and to express willingness to take part in an interview.

It will be explained to the potential participant that entry into the study is entirely voluntary, comments they make will not be individually attributed in any written report, and no aspect of their work or studies will be affected by their decision. It will also be explained that they can withdraw from the study at any time, but attempts will be made to avoid this occurrence. In the event of their withdrawal, it will be explained that their data collected so far cannot be erased and we will seek consent to use the data in the final analyses where appropriate.

Eligibility criteria

Inclusion criteria:
Healthcare professionals or healthcare students (e.g., anyone from the target audience of the e-learning package who is willing to take part in the evaluation) recruited outside of NHS organisations.
Ability to give informed consent.
For the interview they must have accessed the e-learning, provided online consent, and have the ability to attend an individual interview (remotely).

Exclusion criteria:
Not healthcare professional or healthcare student
Not used the e-learning package.

Expected duration of participant participation

Study participants will be participating in the study for:

Stage 1: the duration of a single online survey
Stage 2: the duration of a single interview.
Participants can complete the survey and/or the interview.

Removal of participants from therapy or assessments/Participant Withdrawal

Participants may be withdrawn from the study either at their own request or at the discretion of the Investigator. Participants will be made aware (via the information sheet and consent form) that should they withdraw, the data collected to date cannot be erased and may still be used in the final analysis.

Informed consent

All interview participants will be able to access an online information sheet and provide written informed consent online. Informed consent will be collected from each participant before they undergo an interview. One copy of this will be kept by the participant and one will be kept by the Investigator.

Study treatment and regimen

8 Study Stage 1: The online survey will take place first (a separate stage of the study). A link to the online survey containing information about the survey will be sent by email to our professional networks. A copy of the final survey and study information will be forwarded to the ethics committee for records, once the PPIE stage is complete. Information gathered in the survey will help to inform the final version of (or revisions to) the APUEC package. Assumed consent will be taken for completion of the online survey.

Study Stage 2: The link to the APUEC package will be circulated to our professional networks, together with link to an online information sheet and consent form to take part in an interview to evaluate the package. Those who provide online consent to take part in an interview will provide their contact details, and these will be used to arrange a convenient interview time, at which point the interview PIS will be attached to the booking email.

This is an educational evaluation study which includes no treatment adjustment nor clinical or lifestyle intervention. The interview relates only to their perceptions towards the APUEC digital education package which is an open-access digital learning tool that will be released in early 2022 and so no new interventions are being developed as a part of this research (although we will use information from the study to update the package if needed).

Prior to the start of the semi-structured interview, participants will be asked some brief demographic questions to help with interpretation of the qualitative data and some questions about accessing and using the e-package (usability and utility questions). The investigators will ask questions on: age, gender, line of work or year of study, whether or not they have been involved in health promotion (and specifically alcohol screening or prevention), ethnicity.

The study aims to identify the current alcohol prevention practices of staff working in emergency settings and describe the views of healthcare staff and students towards the APUEC digital training package. In the interviews, the investigators aim to:

- Identify current alcohol prevention practices (including barriers / facilitators) of staff working in emergency settings (survey)
- to gather insight into the reach and use of the APUEC package (educational evaluation).
- identify any facilitators, obstacles or barriers to accessing the e-package (educational evaluation).
- Identify whether there have been any perceived changes in knowledge, confidence or behaviours relating to alcohol prevention (educational evaluation).

Interviews will be facilitated by a member of the project team. We expect the interviews to last approximately 30-40 minutes,although they may be shorter or longer, depending on the discussion that is generated. Discussion will be informed by a semi-structured topic guide.
The interviews will be held by telephone or videoconferencing (e.g., Teams) at a mutually convenient time. Digital audio equipment will be used to record the interview discussion. Recordings will be transcribed in full and anonymised.

This is an educational evaluation and as such we do not anticipate any particular ethical challenges. However, due to the nature of the package content (alcohol screening and prevention) there is some potential that there will be some emotionally challenging issues raised. The interviewers are trained in good clinical practice (GCP). They are sensitive to the potential for COVID-19 and vaccines to be a sensitive topic for some. Facilitators will manage the discussion accordingly and will raise any concerns with the chief investigator in the first instance (who is a chartered psychologist) who can discuss with the package co-developers. If there are issues which cannot be resolved within the study team they will be signposted to appropriate services, and additional resources and sources of information that exist already within the e-learning package, about reducing alcohol consumption and supportive services. We will ensure that participants are aware that they may take a break from the interview should they wish. We will support participants in terminating the interview should they feel unable to continue.

Compliance

For the online survey – participants will be considered to have complied with protocol if they opt to access the survey, then complete it. For the interview - participants will be considered to have complied with the protocol should they attend the interview which they have agreed to attend.

Criteria for terminating study
A failure to recruit sufficient participants to deliver the qualitative interview element of the study design will lead to the study being terminated.

Statistics

9 Methods
Survey data will be analysed using descriptive statistics.
Pre and post e-learning package questions will be analysed using descriptive statistics.
Qualitative data will be analysed using thematic analysis.
Analysis will be undertaken by the project team.

Sample size and justification
We will aim for an approximate total sample of:
Approximately 500 healthcare workers and/or healthcare students (recruited outside of the NHS) to complete the online survey scoping their current practices and establishing training needs.
Approximately 100 healthcare professionals and/or healthcare students (recruited outside of the NHS) who have accessed the e-learning resource and completed pre and post survey questions that are embedded within the resource.
We will interview up to 30 healthcare professionals and/or students (recruited outside of the NHS) who have accessed the e-learning resource about their views towards the resource and any potential impacts on their knowledge, confidence or behaviours. We will endeavour to promote the study materials in diverse areas to maximise recruitment of participants of different genders, level of experience / seniority, occupational group and setting (urgent or emergency care). This will provide information required to evaluate the training package and update the e-learning package in the future.

Assessment of efficacy
N/A (this is not an efficacy study).

Procedures for missing, unused and spurious data
Missing data in the online survey will be reported as missing.
N/A for qualitative interviews.

Definition of populations analysed
All data generated will be included in the analysis.

Adverse events

10 There is no intervention nor period of observation for this study (as we are evaluating what will be an existing educational e-package), so there is no period in which an adverse event might be observed. If Information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Ethics and regulatory aspects

11 ETHICS COMMITTEE AND REGULATORY APPROVALS
The study will not be initiated before the protocol, informed consent forms and the participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider's Research & Development (R&D) department, and the Health Research Authority (HRA) if required.
Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the REC will be informed.
The study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Department of Health Policy Framework for Health and Social Care, 2017.

INFORMED CONSENT AND PARTICIPANT INFORMATION
The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced.

For the qualitative element: participants will provide online informed consent before the person can participate in the study. The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasise to them that consent regarding study participation may be withdrawn at any time without penalty or affecting any benefits to which the participant is otherwise entitled. If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

RECORDS

Transcripts of Audio Recordings. Transcripts will be treated as confidential documents and held securely in accordance with regulations. The investigator will make a separate confidential record of the participant's names to permit identification of all participants enrolled in the study, in accordance with regulatory requirements and for follow-up as required. Transcripts shall be restricted to those personnel approved by the Chief Investigator and recorded on the 'Study Delegation Log.'

DATA PROTECTION

All study staff and investigators will endeavour to protect the rights of the study's participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. Computer held recordings and transcripts will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords (encrypted using a one-way encryption method). Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

INSURANCE AND INDEMNITY

The University of Nottingham as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

STUDY CONDUCT

The Study Coordinator/Academic Supervisor, or where required, a nominated designee of the Sponsor, shall carry out a site systems audit at least yearly and an audit report shall be made to the Study management group.

STUDY DATA

The Principal Investigator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of study data as an ongoing activity.

RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility. The Study Master File and study documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham.This archive shall include all study databases and associated meta-data encryption codes.

DISCONTINUATION OF THE STUDY BY THE SPONSOR

The Sponsor reserves the right to discontinue this study at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons.

STATEMENT OF CONFIDENTIALITY

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above. If information is disclosed during the study that could pose a risk of

harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly. Data generated as a result of this study will be available for inspection on request by University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

Publication and dissemination policy

12 Insight generated here will provide insight into the use, and perceived value of APUEC package, which will allow for the generation of recommendations for health and medical education institutions. We will advocate this at national and international medical education and public health events. We will make use of our strong links (e.g., with Healthy Universities Network, NHS Employers, NHS Confederation, Royal College of Nursing) to make other NHS organisations aware of our findings. We will relay our findings to the membership thorough social media, newsletters and / or email updates sent out by these organisations. We will report the findings at staff conferences and events and publish the results in high quality academic journals.

User and public involvement

13 The package was developed in collaboration with a panel of experts in emergency medicine and nursing, health promotion and public health (including alcohol services). Our evaluation protocol has been reviewed by a healthcare professional and a healthcare trainee. This educational evaluation is in itself demonstrating user and public involvement through the PPIE and survey processes which inform the final version of the digital education package, and the evaluation includes usability testing with the public.

Participant stipend and payment

14 Participants will not be paid to participate in the study, nor receive reimbursement for their time. Data will be collected remotely and therefore participants will not incur any costs for taking part. To help encourage participation in the qualitative interviews, the study information sheet will inform participants that those who take part in an interview will be invited to opt into a prize draw to receive an Amazon voucher of £50 (optional).