Full title:	**Programme of research for Alcohol Care Teams (ACTs): Impact, Value and Effectiveness**
Short title:	ProACTIVE
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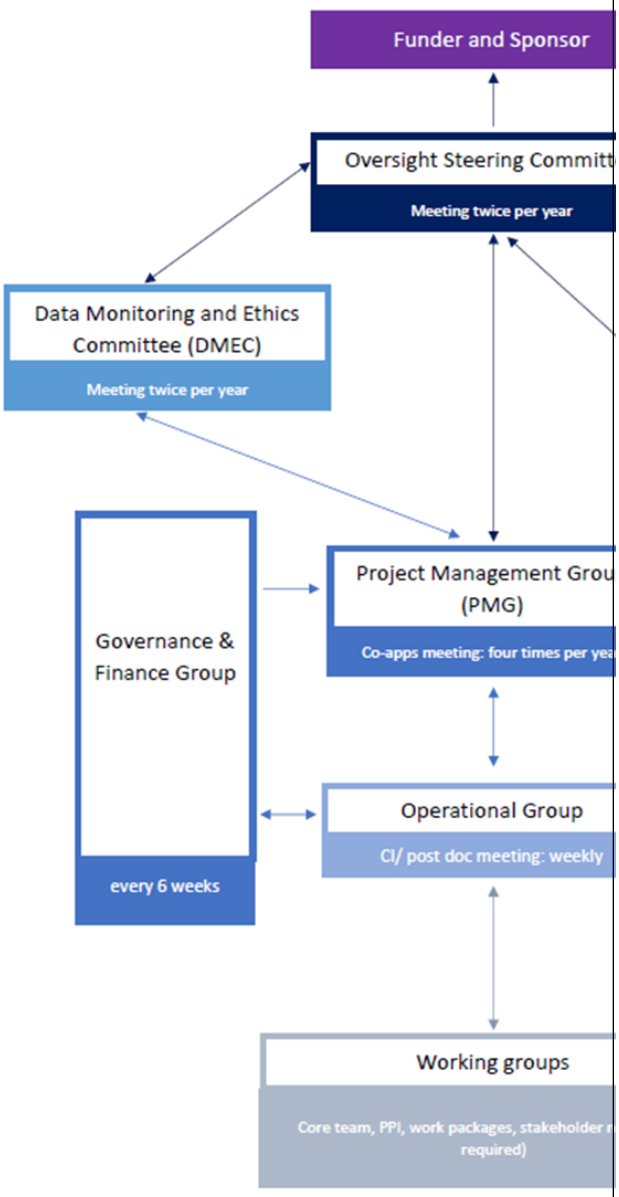
Detailed Research Plan Version History

Version Number	Date	Update finalised by (insert name)	Reason for update
1.0	30/10/2022	Professor Julia Sinclair & Professor Thomas Phillips (co-CIs)	• N/A
1.1	15/03/2023	Professor Julia Sinclair & Professor Thomas Phillips (co-CIs)	• WP1b has been further developed to review the literature to determine the evidence base for the components of ACTs (and equivalent services in the international literature) and develop a consensus on the components of care that may be delivered by ACTs which could then be implemented in practice (page 17). • The GANTT chart (Appendix 1) has been revised to accommodate an extended timeline for completing WP1b to facilitate the preparation for, and initiation of, the quasi-experimental study, which is time critical for the overall programme. The updated reporting structure has been added to • Appendix 2. • The 'PPI approach' document, detailing the principles of PPI involvement has been

			added to  ProACTIVE Reporting Structure, Version 2, 17/Mar/2023 • •
1.2	19/03/2024		• Changed the term ‘programme protocol’ back to ‘Detailed Research Plan’. • In WP1b, the Public Co-applicant (PK) was replaced by Public Consultant (AB) due to PK's resignation and AB assuming the role.

			• In WP3, removed family involvement from the micro-level analysis in the qualitative investigation of patient interviews. • Updated the Gantt chart to reflect the latest version. • Removed the statement the UoS was the sponsor of the whole programme from page 1. Added a Work Packages diagram to Appendix 3 and a table of ethics approvals, detailing sponsorship for each work package as originally intended.

Overview of Research Project Work Packages: Ethics Approvals, Sponsorships, and Protocol Documents

Work Packages	Ethics Committee /organisation	Approval/ID number	Sponsorship	Protocol
WP1a	IRAS[1]	322240	University of Southampton	Appendix 4 Version 1.0 February 2023
	ERGO[2]	72815		
WP1b	ERGO	91863	University of Southampton	Appendix 5 Version 1.1 February 2024
WP2a	FHS[3]	22-23.97	University of Hull	Appendix 6 Version 1.1 November 2023
	IRAS	330296		
	REC[4]	23/LO/0797		
WP3 (ACTION peer review observation, decision maker interviews)	IRAS	322240	University of Southampton	Appendix 4 Version 1.0 February 2023
	ERGO	72815		
WP3 (patient, staff interviews and site observation)	IRAS	333788	University of Southampton	Appendix 7 Version 1.2 December 2023
	ERGO	86766		

[1] IRAS - Integrated Research Application System
[2] ERGO - Ethics and Research Governance Online
[3] FHS - Faculty of Health Sciences
[4] REC - Research Ethics Committee

RESEARCH REFERENCE NUMBER: NIHR152084
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SIGNATURE PAGE

The undersigned confirm that the following plan has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved plan and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this document will be explained.

Co-Chief Investigator:

Date: 27th March 2024

Signature: .....

Name: (please print):

Professor Julia Sinclair….....

Co-Chief Investigator:

Signature: ..... 

Date: 28th March 2024

Name: (please print):

Professor Tom Phillips.…….....

ProACTIVE Abbreviations and glossary of terms:

ACT	Alcohol Care Team
ACTION	Alcohol Care Team Innovation and Optimisation Network
AMAU	Acute Medical Assessment Unit
APEASE	Acceptability, Practicability, Effectiveness, Affordability, Side-effects and Equity
ARBI	Alcohol-Related Brain Injury
ArLD	Alcohol-related Liver Disease
AUDIT-C	Alcohol Use Identification Test
CICI	Context and Implementation of Complex Interventions
CNS	Central Nervous System
CSRI	Client Service Receipt Inventory
DARS	Data Access Request Service
DMEC	Data Monitoring and Ethics Committee
ED	Emergency Department
EDC	Electronic Data Capture
GHW	Gastro/Hepatology Wards
GMW	General Medical Wards
HES	Hospital Episode Statistics
HES-APC	Hospital Episode Statistics – Admitted Patient Care
HHTU	Hull Health Trials Unit
HRG	Hospital Resource Group
ICB	Integrated Care Board
ICS	Integrated Care System
IMD	Index of Multiple Deprivation
ITS	Interrupted Time Series
LA	Local Authorities
LTP	Long Term Plan
MRC	Medical Research Council
NDTMS	National Drug (and alcohol) Treatment Monitoring System
NHS	National Health Service
NHSEI	NHS Improvement and NHS England
NIHR	National Institute for Health and Care Research
NN	Nearest Neighbour matching
oACT	Optimal Alcohol Care Team
OHID	Office for Health Improvement and Disparities
ONS	Office for National Statistics
PAG	Public Advisory Group
PHE	Public Health England
PMG	Project Management Group

PPI	Public and Patient Involvement
ProACTIVE	Programme of research for Alcohol Care Teams (ACTs): Impact, Value and Effectiveness
PSM	Propensity Score Matching
QALY	Quality Adjusted Life Year
RCT	Randomised Controlled Trial
SADQ	Severity of Alcohol Dependence Questionnaire
SoECAT	Schedule of Events Cost Attribution Template
TLFB	Time Line Follow Back
WP	Work Package

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1. Lay summary

Alcohol causes over 60 different physical, and mental health conditions. In England, more people are being admitted to hospital and dying from alcohol-related disease than ever before. There has been more research into what helps people with severe alcohol dependence who go to specialist community services, but much less is known about the 1 in 10 people admitted to acute hospitals who are also alcohol dependent, often not accessing treatment.

Alcohol Care Teams (ACTs) have developed in response to local need, but all in different ways. As part of the National Health Service (NHS) long-term plan, ACTs are being developed in 25% of hospitals with the greatest need. The next step is to understand which models of service are most supportive of patients, and if they are a good use of NHS resources to improve outcomes and reduce health inequalities.

We have designed a programme of research that will help answer these questions. We will first map the ACT provision across the country, then recruit a panel of experts to categorise the different kinds of ACT models. This will allow for comparisons between ACT models that will investigate the impact of different kinds of ACTs on hospital alcohol admissions. We will also recruit patients from different hospitals to get patient data after six-months to record any changes in alcohol consumption, general health and wellbeing and NHS hospital use. Given the different stages of development of ACTs, this will help us identify what works best, for whom. Statistical analyses estimating costs of different ACTs and how they relate to patient outcomes will help inform which ACT models are the best value.

The voices of people with lived experiences are vital, so we have included patient and public co-production as central to our research. We will include a strong qualitative evaluation and use case-studies, and interviews with decision makers, staff and patients to understand the challenges for ACTs at national, regional and local level. This programme will enable us, for the first time, to define the necessary components of an ACT, where and how they work best, and with which group of patients. Central to this is the development of an ACT patient and public involvement network, which is currently lacking. Our findings will increase our understanding of which interventions are most helpful to this under-served patient group, as well as providing evidence and tools to policy makers and commissioners about the best use of NHS funds.

2. Scientific Abstract

Alcohol-related hospital admissions continue to rise, with estimates that 10% of patients admitted to acute hospitals may be alcohol dependent (AD). Yet, there remains considerable variation in provision of Alcohol Care Teams (ACTs) in England, and a limited evidence base for understanding their clinical effectiveness. The NHS long-term plan has committed to develop existing services and establish new teams in 25% of hospitals in greatest need by 2024.

The ProACTIVE research programme is a multi-disciplinary, integrated, mixed-methods study designed to evaluate the impact of ACTs at macro (policy), meso (health system) and micro (patient) level. It will categorise models of ACTs, define the components which best support the identification, and cost-effective management of hospitalised adults with AD, and facilitate rapid dissemination of the results.
The ProACTIVE team is uniquely placed to deliver this national evaluation, combining expertise in health service and delivery methods, data and implementation science, clinical management of AD, and advocacy of lived experience. ProACTIVE has four interconnected work packages (WP):

WP1 will build the first comprehensive national database of ACT provision in England, identify local stakeholders, define the range of components of care, agree a taxonomy for ACT interventions, and explore the reliability and linkage of nationally available data.

WP2 will evaluate the clinical and cost-effectiveness of ACTs, using a quasi-experimental naturalistic study of three 'optimal' ACTs and three 'minimal'/no ACT sites, following-up patients for six months to evaluate the micro level impact of ACTs. Meso level ACT impacts (e.g., re-admission rates, length of stay) will be assessed by an interrupted time series analysis using nationally available data.

A parallel exercise will assess the cost-effectiveness of ACTs at both meso and micro levels. As ACT effects may take time to emerge (e.g., impacts on health inequalities), a model will be built to generate estimates of how the health outcomes vary across socioeconomic groups, and the impact of introducing (or removing) an ACT on alcohol-related health inequalities.

WP3 is a qualitative evaluation of ACTs, using an organisational ethnographic case study design to identify factors at macro, meso and micro levels that have shaped the composition, delivery, and impact of ACTs. The integrated PPI team (PPI co-ordinator (MK) researchers (KC, SU) and CI (JS)), will ensure that each element of the research embraces co-design principles and integrates the experience of patients into the enquiry.

WP4 will facilitate timely synthesis of findings from each phase of the evaluation, using the 'Context and Implementation of Complex Interventions' framework, and work with stakeholders to generate guiding principles for an optimised ACT, and toolkit for best practice in developing sustainable, patient focussed services.

Defining necessary components of an ACT – where and how they work best, and with whom is essential groundwork to grow the evidence base for which interventions are effective in this underserved patient group. Central to this, is the development of an ACT Stakeholder network to co-produce evidence and tools with patients, policy makers and commissioners about the best use of NHS funds in this area.

3. Background

In England, alcohol-related hospital admissions rose to over 1.26m in 2018/19, 155% increase over15 years (1). Recent estimates suggest overall 1 in 5 patients admitted to hospital drink at harmful levels, and 1 in 10 may be alcohol dependent (2). A disproportionate impact of alcohol on the National Health Service (NHS) is exerted by those with chronic alcohol disorders accessing care via emergency departments (ED) (3). Alcohol-related disorders have been estimated to cost the NHS £3.5bn per year (4), with most of these costs related to ED attendances and hospital admissions, in addition to the adverse impacts on patients requiring unscheduled acute care for complex co-morbid conditions. These data clearly demonstrate the need for secondary-care settings to have skills, resources, and structures in place to respond effectively to increasing demand.

Alcohol liaison services have evolved slowly in response to rising alcohol related harm. In 2013, a survey by Public Health England (PHE) of 191 general hospitals identified 73% reported some level of specialist alcohol provision (5). These services fell into three broad models:1) hospital based multi-disciplinary Alcohol Care Teams (ACTs); 2) an in-reach team/worker provided by community addiction services; and 3) a high impact user service (e.g., assertive care provision for a small complex group of patients). Clinical leadership was found to be provided by ward consultants (e.g., hepatologists), ED physicians or addiction specialists. The survey identified 30 (15.7%) hospitals had developed a multidisciplinary ACT but found significant variation in scope and level of intervention provided (5).

The clinical consensus is that multidisciplinary ACTs, operating within broader care pathways, are needed to address the rising impact of alcohol-related harm and emergency admissions to acute hospitals (5,6). But, how these are operationalised, and what are their necessary components is less well defined. ACTs are liaison services which engage in a range of activities at both the organisational (meso) and individual patient (micro) level. This includes training non-specialist staff, developing system protocols, providing direct specialist clinical care (e.g. facilitating medically assisted withdrawal and delivering psychosocial interventions) and liaising with other hospital and community services (6,7). Taken together, these contribute to a pathway of care that aims to support patients to sustain healthier drinking behaviours or become alcohol-free.

In 2018, prior to the launch of the NHS Long Term Plan (LTP; 8) it was estimated the number of multidisciplinary ACTs providing a range of interventions (i.e., screening, brief interventions, comprehensive assessment, medically managed alcohol withdrawal, etc), had risen to 60, with

variations in scope based on size of hospital, local need and available funding. Importantly, a number of these multidisciplinary ACTs demonstrated that 'optimal' services operating 7-days per week, offering a full range of patient level interventions, as well as staff training and collaborative care with community providers, are cost effective. One case study (from Royal Bolton Hospital NHS Foundation Trust) identified a return on investment of £3.85 for each £1 invested in the ACT service (9).

The NHS LTP (8) has committed to spend £26m over four years (until mid-2024) to 'optimise' ACTs through the development of existing services and the establishment of new teams in the 25% of hospitals in greatest need in England. In this context 'optimisation' involves funding to offer a 7-day service to deliver a range of patient and system level interventions to improve the identification and management of alcohol dependent patients (10). A range of service models have evolved, supported by existing clinical guidelines, to assess and treat individuals with alcohol use disorders (11,12). Comparisons between well-established comprehensive, multidisciplinary ACTs offering a 7-day service and those at different stages of development, allows for evaluation of the most effective and cost-effective components and models of ACTs.

Throughout this plan we use the term ACT to describe all forms of hospital-based alcohol-care provision;

- 'optimal ACT' (oACT) for comprehensive 7-day multidisciplinary services that meet all criteria defined by NHS Improvement and NHS England (NHSEI ;10),
- 'developing ACT' for non-7-day services, delivering some intervention components', and
- 'minimal ACT' for an identified but rudimentary provision.

3.1. Evidence explaining why this research is needed now

The development and evaluation of ACTs under the NHS Long Term Plan coincides with the largest investment in drug and alcohol treatment for over a decade and together provides an opportunity to ensure sustainable systems of care for those with alcohol dependence that are built on the best available evidence. Following publication of the Dame Carol Black Independent Review (76) of drug treatment the UK Government announced a significant increase in funding of specialist addiction services. As part of this investment, it was announced in April 2022 that local authorities (LA) across England would receive £85.7million in additional grants to support drug and alcohol treatment recovery services, including inpatient detoxification for 2022/2023 (77). In total the strategy is backed by a new investment of almost £780 million for treatment (78). Consequently, there is increasing interest as how the development of Alcohol Care Teams can be supported within the wider system of care. Meetings with commissioners have revealed a desire to support the emerging models increasing access to specialist treatment which has experienced a recent decline in access and engagement. The timeliness of this project could not be better placed to help inform commissioning decisions and the development of services based on the available evidence (6; 79).

Alcohol dependence is a highly stigmatised condition (13), and patients' access to, and experience of healthcare is significantly affected by both internalised (felt) and external (enacted) stigma towards

them (14, 15) which are likely to have an impact on their health outcomes (16). This has become more pressing with the impact of the pandemic, which has seen increased rates of 'higher risk' drinking (17), and a 20% rise in alcohol-specific mortality since 2019 to the highest since records began, significantly worse in the most deprived areas of England (18). The development of ACTs was driven primarily from a narrow service-use model of the short-term management of alcohol dependence within an acute setting (12), based on individual hospital case-studies, and there has been no robust national evaluation of the impact of implementing ACTs more broadly. The ACT is a classic 'black box' where a complex system of interventions impact on the wider health and social care systems (macro level); the hospital trust and integrated care system (ICS) in which they are based (meso level); and impact for the individual patient (micro level).

The efficacy of pharmacological and psychological interventions in people with moderate to severe alcohol dependence presenting to specialist community addiction treatment settings is well established (11), as are the effectiveness of alcohol brief interventions for people with increased risk drinking across a range of health settings (19). However, there is very little evidence on the range of treatment needs of patients who may be seen by ACTs, how to define and describe the different components that constitute the work of an ACT (at both meso and micro levels), a systematic way of recording patient outcomes, or even what may be the most valid outcomes to measure.

In terms of the NHS LTP ACT programme, the first wave of twelve sites (one per region) was based on evidence of local alcohol-related harm (20), system readiness, and clinical leadership. The second wave of 33 acute hospital sites was awarded in 2021 for development over the next year, although the impact of the pandemic on NHS transformation plans has delayed this timescale. The NHS LTP support for ACTs has broken the cycle of 'no robust evidence, no sustained provision' and intend funding to be continued by local integrated care boards (ICB) at the end of the programme. For this to happen, there needs to be high-quality empirical data testing the assumptions of currently defined 'optimal' ACT components, an understanding of the processes, barriers and facilitators to cost-effective and sustainable functioning, the impact ACTs have on health inequalities and a valid way of defining and systematically recording outcomes.

Underpinning this project and central to the development of a national ACT programme is Public Contributor involvement, bringing insight and understanding from underserved groups (21) by asking 'optimal for whom?', targeting unconscious bias and stigma in the enquiry, and highlighting variation in local need. This approach will ensure co-production of evidence and tools with patients, policy makers and commissioners about the best use of NHS funds in this area, contributing to the design of a programme of research that will inform the intended re-commissioning of ACTs in 2025.

4. Aims and objectives

4.1. Study aims:

- Determine the spectrum of characteristics and care needs of patients who may benefit from ACTs.
- Identify the components and resource implications of clinical- and cost-effective models of ACTs across England, which best support the identification, and management of hospitalised adults with alcohol dependence.
- Work with Stakeholders to co-produce and ensure rapid dissemination of outputs to inform macro and meso level policy decisions, clinical best practice, and future research priorities.

4.2. Objectives:

Macro (policy) level

- Build a comprehensive national ACT database to identify level of provision that can be mapped to local need and inform data driven approaches of future work
- Produce evidence of impact of ACTs on cost, health outcomes and inequalities to inform future policy
- Develop a National ACT Stakeholder Network, including people with lived experience, to address the lack of representation of this stigmatised and underserved group in research and policy making
- Develop regional research networks to best identify the underserved groups in this area and link in with national implementation networks

Meso (system) level

- Map variations in ACT components, models of care and commissioning processes
- Explore the effectiveness and cost-effectiveness of ACTs and model impact over time
- Identify barriers and facilitators to ACT implementation from a range of perspectives
- Engage stakeholders to integrate data-informed outputs with local expertise to inform commissioning

Micro (individual) level

- Describe characteristics and cohorts of patients who may benefit from ACTs
- Understand impact of ACTs on patient experience, access to aftercare, and outcomes
- Active involvement of a wide range of stakeholders throughout the research process to bring insights currently lacking

5. Research Methods

This is an integrated mixed method research programme with four interacting work packages co-ordinated by an expert team (including public contributors) with a track record of working with each other and successfully delivering complex health research projects. The evaluation will follow the updated MRC framework for complex interventions (22) - working with stakeholders to describe the intervention, consider the context in which ACTs are being delivered, determine outcomes for evaluation, and use appropriate methods for the ACT 'natural experiment' that is already being implemented.

ACTs are a prime example of a complex intervention, involving multiple and interacting components, delivered in busy unpredictable settings by different types of providers, working with patients who may have other complicated needs and comorbidities (22). An overview logic model (Fig 1.) for the determinants and potential impacts of ACTs on alcohol-related harm at macro, meso and micro levels is shown below together with how the objectives of the ProACTIVE programme will evaluate them. The four work packages (WP) are:

WP1: Build a national ACT database: A comprehensive cross-sectional survey of ACTs will generate a detailed profile of ACT services and activities currently operating within the NHS, including any locally identified public contributors involved in ACT design and delivery. Consensus development methods (for example, a systematic review and modified-Delphi process) will be used to establish consensus on definitions of the components of the ACT 'black box', as these may be developed in the form of 'care bundles', incorporating the patient perspective, including any gaps.

WP2: Evaluation of the clinical and cost-effectiveness of ACTs: A quasi-experimental naturalistic study of three 'optimal' ACTs (oACT) and three 'minimal'/no ACT sites will follow up patients for six months to evaluate the micro level impact of ACTs. To draw causal inferences of the relative effect of oACTs, a counterfactual control group will be derived, using propensity score matching. Meso level ACT impacts will be assessed by an interrupted time series analysis using nationally available routine administrative data (Hospital Episode Statistics (HES)) of hospitals with ACTs (determined in WP1) examining re-admission rates, length of stay, etc. These results will inform the short-term cost-effectiveness analysis and modelling of long-term impact of ACTs at both micro and miso levels.

WP3: Qualitative evaluation of ACTs: Using an organisational ethnographic case study design (23) to identify factors at macro, meso and micro levels that have shaped the composition, delivery, and impact of ACTs. This will triangulate multiple data sources (documentary analysis, observation, interviews), producing 'pen portraits' of sites to facilitate within and cross-site analysis (24). The integrated PPI team (consisting of PPI co-ordinator (MK) researchers (KC, SU) and CI (JS)) will ensure that each element of the research embraces co-design principles and the views of patients and others with lived experience.

WP4: Data integration, dissemination and recommendations for future policy and practice

We will use the Context and Implementation of Complex Interventions (CICI) framework to guide analysis and interpretation of evaluation data (25). The CICI framework aims to address implementation and context of a complex intervention in an integrated and relational fashion and comprises three dimensions:

- **Context** (geographical, epidemiological, socio-cultural, socio-economic, ethical, legal political);
- **Implementation** (theory, process, strategies, agents and outcomes);
- **Setting** (how the intervention and its implementation interact with context).

There is a detailed plan for integration of emerging evidence, and co-production of outputs to ensure targeted and timely dissemination of findings for future policy and practice.

- Appendix 3.

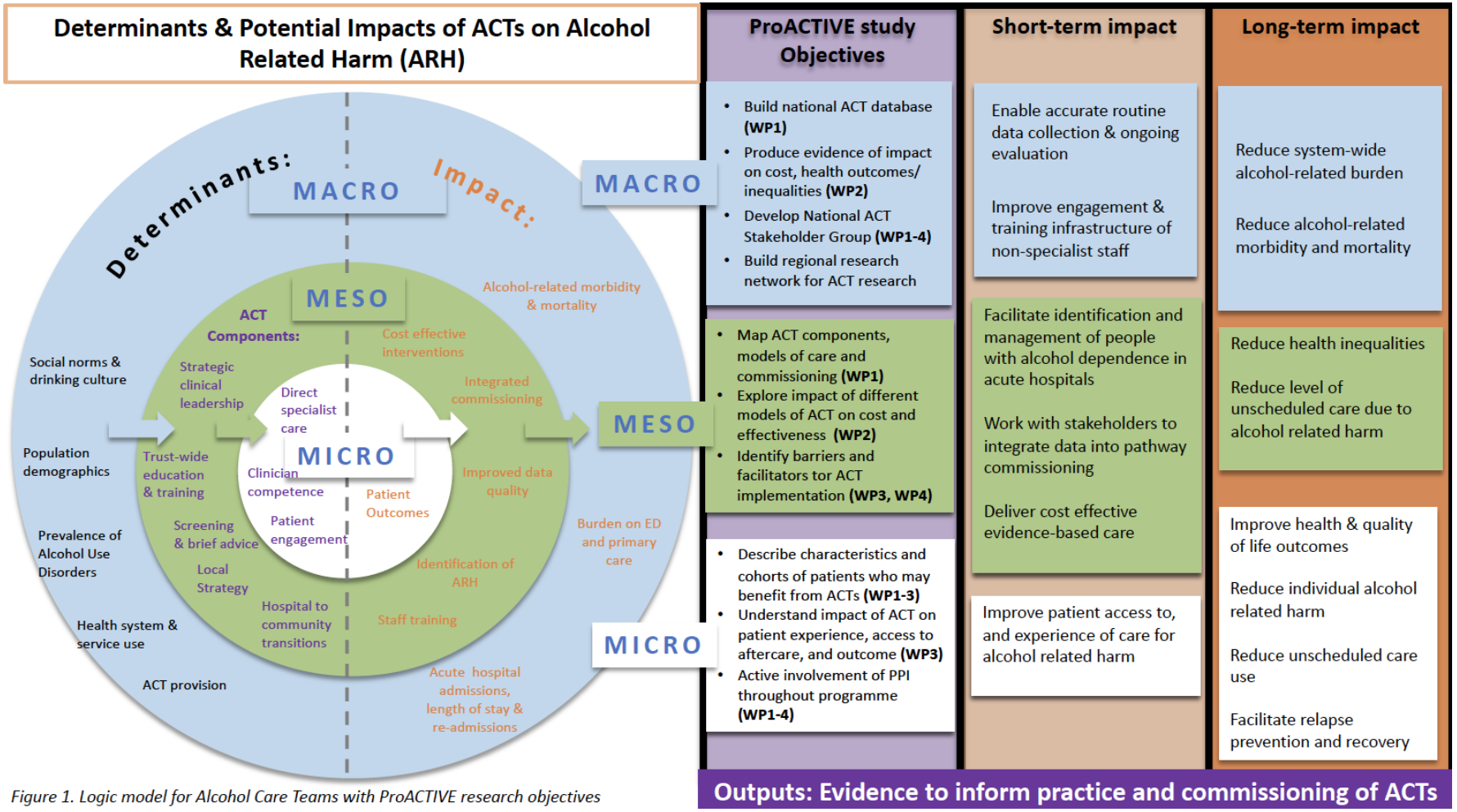


Figure 1. Logic model for Alcohol Care Teams with ProACTIVE research objectives

6. WP1: Build a national ACT database

Rationale: The challenges of managing unscheduled admissions of short duration (2,3) has required ACTs to evolve clinical practice and pathways (26) outside of clinical guidelines. Although an 'optimal model' has recently been described for ACTs (6,7,27) WP1 will systematically identify and clearly define the current level, scope and function of ACTs working within acute hospitals in England, as well as exploring relevant available data sources. This will be integrated with local knowledge and population factors to inform data driven approaches of future work packages. Routine healthcare data provides some evidence of the impact of alcohol-related harm on hospital admissions and specialist community alcohol services, but involvement of ACTs is not routinely collected or attributed to clinical cases. Understanding the perspective of this underserved patient group is vital and has not previously been explored. WP1 has three strands, which will run in parallel:

a) Mapping of current configurations of ACTs nationally
b) Establish a taxonomy to describe the components of ACTs currently delivered, incorporating the patient perspective on what is most important, and any gaps.
c) Review of available data sources

6.1. WP1a: Mapping of current configurations of ACTs nationally

Methods: Cross-sectional survey of all (n=218) acute hospital NHS Trusts in England in two phases: an initial scoping survey will collect data to screen for sites that have any components of ACT, and then a more in-depth appraisal of sites with any kind of ACT.

WP1a will generate a detailed profile of ACT services and activities currently operating within the NHS; defining the stage of development, scope, function, and reach within their local health system. The research team will draw on their extensive experience of similar large surveys (28-30) and established collaborations with Office for Health Improvement and Disparities (OHID) and NHSEI. Extending previous national PHE surveys of hospital-based alcohol services (5) and working closely with national and regional leads from OHID and NHSEI, researchers will approach each Trust to establish contact with key stakeholders. Each ACT will also be asked to provide information on other services that form part of the pathway for patients seen by them within their local health system who will also be contacted to contribute data to the survey.

An online tool will be developed for the in-depth survey, by the Hull Health Trials Unit (HHTU) with content generated by the programme team (including the integrated PPI team), and informal consultation with stakeholders. The survey will be built using RedCap Cloud, a cloud-based electronic data capture (EDC) system which is within scope of the HHTU NHS Data Security and Protection Toolkit (Organisation Code-EE133824-HHTU). Access will be granted to the survey at a site level to enable online completion. Researchers will check data quality and follow-up missing data and non-completion with the named informant, offering completion via telephone with a researcher (shown to help maximise response rate). The survey tool will consider three core domains, i) description of the service, workforce and other resource use, ii) delivery of NHSEI defined core components (7)

reach within hospital, and iii) reported clinical activity. The PPI coordinator will work along-side the research team to identify any service-user groups known to local areas and engage with them.

6.2. WP1b: Establishing a taxonomy for ACTs

Methods: Three interconnected phases:

1. Work with the integrated PPI team (consisting of Public consultant (AB), PPI co-ordinator (MK) researchers (KC, SU) and CI (JS) and evolving stakeholder network (including those with lived experience), to understand key-components of an ACT from the patient perspective, adding to data generated in WP1a above.
2. Define the currently delivered component parts of the ACT 'black box' using data from WP1a and identify any gaps, including from the patient perspective
3. Use a modified Delphi process to:
    a. Review the literature to determine the evidence base for the components of ACTs (and equivalent services in the international literature).
    b. Discuss what is entailed in different ACT components for different patient groups (e.g. those with Alcohol-related Liver Disease (ArLD), Alcohol-Related Brain Injury (ARBI), comorbid mental disorder, older adults etc) and from different perspectives (evidence base, patient and clinician experience) in an initial face-to-face meeting.
    c. Establish consensus on the components that comprise the essential components of the ACT 'black box', operationalised as components for 'care bundles' using iterations conducted virtually as per standard Delphi methodology.

Given the organic evolution of ACTs there are no standard definitions for the range of activities undertaken, resulting in terms (e.g. brief intervention) being used variably and interchangeably. There is a need for consensus between the research team, stakeholder groups, and clinical sites about the range of ACT activities undertaken and how these are broadly defined. An over-inclusive sample of components and interventions that are essential for ACTs will be identified by the panellists. A group of 20 panellists (ensuring a maximum variation sample) will be recruited from clinicians working in ACTs across England, stakeholder groups (including those with expertise in ArLD, ARBI, older adults and comorbid mental disorder) and the PPI team, to undertake a consensus development process.

Panellists will be asked to commit to a face-to-face meeting and to identify an overinclusive list of the components seen as essential to the effective functioning of an ACT. They will be asked to agree definitions of what each component entails, and rate each component as to how essential it is to be included in an ACT. Initial definitions will be reviewed by all panellists and modified. Future iterations will be completed virtually, panellists will receive group ratings for each component and free text comments, they will then go through each component from the overinclusive list of ACT interventions and rate how essential they are to an ACT. This will form the basis to establish consensus on which are the essential components of the ACT 'black box'. The final procedure will be detailed in a separate document (Appendix 5 - WP1b protocol).

There are a number of modifications to the Delphi process that have been used in healthcare over the years, one of which has been to start the process with an in-person meeting in which the participants meet to discuss the process, fully understand the specific context of what they will be asked to rate in subsequent rounds and resolve uncertainty or any ambiguities in the wording of the questionnaire (27, 60, 61, 80).

This 'in person' first round modification has been used successfully in a similar study needing to agree a common taxonomy for a complex 'black box' intervention that was being developed in different pilot sites (61). It was found to be a necessary pre-requisite in understanding and gaining some common ground in terms of understanding how components of care with similar names varied, or different names were in fact the same thing (61). Given the complexities of the ACT 'black box' and the need to have a robust way to ensure that all core components are accurately described and agreed (to facilitate future multicentre research both in this programme and beyond), this in-person first stage modification to the Delphi process including a diverse range of ACT clinicians (and people with lived experience) is an essential part of this modified Delphi process, prior to the survey rounds which will be undertaken by the same individuals.

6.3. WP1c: Review of Data Sources to inform WP2:

To date the effectiveness of ACTs has primarily been established using cost-offset analysis calculated through admission avoidance in single site studies using routinely recorded hospital data that examine the impact of patients seen by ACTs (9,31). There are known challenges of working with data for this population (missing data, correct coding) and variation in what is routinely collected at sites. Measures incorporated within a variety of data sources will be assessed for their ability to demonstrate the impact of ACT activity at a Trust or ICB level for use in WP2. The utility of data sources will be based on the coverage and validation of measures and metrics within each identified dataset through review of the datasets and their data dictionaries. Having selected data sources, HHTU will lead the review of the governance arrangements for access, storage and processing of data.

Routine administrative data sources (including hospital episode statistics – admitted patient care (HES-APC) records) for the assessment of ACT and non-ACT hospital sites will be sought via a data access request service (DARS) application to NHS Digital. The research group has extensive experience in conducting epidemiological analysis and health economic evaluations using routine administrative health and related data in this area (2, 3, 32-37), and HHTU have experience and facilities to handle these large datasets, and an established relationship with NHS Digital through existing data agreements. The results will help address questions that will inform the protocols for WP2 including: coding and methods/screening tools used for identification of patients as alcohol dependent; whether it is possible to link with other related data sources e.g. accident and emergency records, National Drug (and Alcohol) Treatment Monitoring System (NDTMS); and prescribing data.

Outputs from WP1:□ □

- Formation of a national stakeholder network including people with lived experience of alcohol dependence managed in a hospital setting, to engage with throughout all work-packages.
- Establish an up-to-date, comprehensive directory of ACT services.
- Overview of the essential components needed for an effective ACT from a range of perspectives.
- Inform the selection of ACTs for WP2a, WP2b, WP3, and resource inputs for WP2c.
- Identify documents and potential participants for WP3.

7. WP2: Evaluation of the Clinical and Cost-Effectiveness of ACTs

7.1. WP2a: Investigate the impact of ACTs on micro-level outcomes:

Rationale: The aim of this work package is to provide estimates of the effect of an established 'optimal ACT' (oACT), defined as part of WP1, on individual participant outcomes. This is a resource intensive, but essential part of programme which address a number of key limitations with the available data. First there is substantial variation in the recording of alcohol-specific conditions in people admitted to acute hospitals, which limits the usefulness of national routinely collected data particularly when focusing on individual outcomes. Second, there is no integrated system for recording alcohol-specific and alcohol-related outcomes post hospital discharge. Therefore, an essential part of this programme is to collect micro-level data on patients seen by an ACT. This will allow us to describe the spectrum of patient characteristics and the relationship between any interventions delivered and their outcomes over time.

The randomised controlled trial (RCT) is considered the 'gold-standard' for estimating the causal effect of an intervention. The act of randomisation ensures appropriate balance between intervention and control groups in terms of observed and unobserved measures, and any differences post-intervention can be attributed to the intervention. In this study a randomised design is not feasible or practical for a number of reasons. First ACTs already exist in a variety of forms so we cannot start with a tabula rasa. Second those ACTs that already exist have taken a great deal of time to mature and be embedded within the health care system. While we gave significant thought to the possibility of conducting a form of RCT, possibly a stepped wedge RCT, we feel that time, costs and a desire to produce pragmatic and generalisable findings requires an alternative methodological approach. A well designed quasi-experimental approach can provide evidence of the relative effectiveness of an intervention when compared with a control, and Medical Research Council (MRC) Complex Interventions guidance acknowledge that designs other than RCTs are considered appropriate for 'natural experiments' when interventions are being implemented already (22), as is the case with ACTs. The key issue is that the lack of randomisation may mean the baseline characteristics of the groups are not comparable and any effects estimated may potentially be biased. In order to address this potential bias we propose to generate an equivalent control group using a propensity score matching approach (38).

The propensity score, derived from baseline covariates in the intervention groups using a logistic regression approach, is a balancing score. Hence, in a set of subjects who all have the same propensity score, the overall distribution of baseline covariates will be the same between intervention and control groups. This allows a non-randomised study to mimic the characteristics of a randomised study with both intervention and control groups.

Propensity Score Matching (PSM): Rosenbaum and Rubin (38) proposed PSM as a method to reduce the bias in the estimation of treatment effects with observational data. The quasi-experimental research package (WP2a) aims to recruit 175 individuals with alcohol dependence from 3 ACT hospitals. Those recruited will be consenting adults admitted to hospital drawn from three main clinical wards/units (i.e. Acute Medical Assessment Unit (AMAU), General Medical Wards (GMW), Gastro/Hepatology Wards (GHW) – see response to bullet point c). Participants will be screened by ACT staff, be capacitous, and agree to complete baseline questionnaires and 6-month follow-up surveys. The 6-month outcomes will compare outcomes from participants recruited from 3 control hospitals (non-ACT). These control hospitals will recruit 350 adult participants with alcohol dependence drawn from the same clinical settings, using the same inclusion/exclusion criteria, thereby emulating the ACT activity. The primary analysis will establish the mean group differences in alcohol consumption in the previous 28 days at 6 months (the gold standard outcome for alcohol treatment trials). Participants from the intervention hospital will be matched to individuals within the control hospital pool using propensity scores.

Propensity score matching is a statistical technique designed to match a treated group with an untreated control group in order to estimate the effect of a treatment. The method employs baseline covariates such as demographics, alcohol use severity and associated problems that predict changes in alcohol use at 6 months. A predictive model is generated for the intervention group and the covariates of this model are then applied to the control sample to select a similar population, as the covariates of interest are only known at the end of sampling it is usual to have a larger pool of potential matches in the control group. The propensity score is the probability of assignment to being a comparable case, given the observed covariates. This allows for the average treatment effect to be estimated for each group, participants from intervention hospitals (ACT-hospitals) versus controls (participants from non-ACT hospitals).

There are a number of matching algorithms that can be employed when using PSM. The most straightforward matching estimator is **Nearest Neighbour (NN) matching**. Each individual from the comparison group is chosen as a matching partner for a treated individual that is closest in terms of propensity score. However, the NN approach faces the risk of bad matches, which can be avoided using **Calliper Matching** that imposes a tolerance level on the maximum propensity score distance (calliper) to improve the matching quality (86). Applying calliper matching means that the individual from the comparison group is chosen as a matching partner for a treated individual that lies within the calliper. Hence, the matching procedure is conducted once the data has been collected and not pre-specified. In keeping with previous studies, we have specified that the callipers of width 0.2 of the standard deviation of the width of the logit propensity score (87).

Methods: Our intervention group will involve three hospitals identified as having an oACT. In order to maximise generalisability, we aim to recruit oACTs from areas of high alcohol dependence prevalence (i.e. North-East England, Humberside), low alcohol prevalence (i.e. East/ South East) and an urban conurbation with a diverse ethnic population (i.e. Birmingham, Manchester). Our control group will consist of three hospitals matched for hospital size and population demographics with no ACT intervention.

In oACT hospitals all alcohol dependent patients seen by the ACT over the recruitment period will be assessed and asked to consent. In the non-ACT hospitals, we will implement a recruitment strategy that emulates the inclusion criteria for ACT intervention and approach patients who would have been seen by an ACT if one existed. The actual criteria will be defined during WP1 and where necessary recruitment processes will be adjusted.

Recruitment process in intervention and control hospitals

The primary research will recruit 175 participants from three ACT hospitals selected from those sites identified in WP1, additionally 350 participants will be recruited from three non-ACT hospitals. Participants recruited from the ACT hospitals will initially be approached by ACT staff with patients verbally consenting to be approached by a trained research worker (employed by the University of Hull) who will be allocated to each ACT/hospital. The inclusion criteria will be adults, with alcohol dependence, admitted and recruited during their hospital admission having been screened as potentially eligible by the clinical ward team and/or ACT as part of their clinical assessment. Whilst the national adult community prevalence for alcohol dependence is estimated at 1.35% (95%CI 1.11-1.71) there is considerable range across local authorities from 0.65% (95%CI 0.43-1.03) to 3.91% (95%CI 1.51-9.51) (36). There is a significant positive correlation between community prevalence for alcohol dependence and hospital admissions, with hospital-based prevalence being magnified due the causal relationship between excessive and prolonged alcohol use and multiple co-morbid diseases and conditions (81). A recent meta-analysis conducted by a member of our research team has identified that 10.25% (95% CI = 7.06–13.96%) involve alcohol dependence (2). The evidence from administrative data and clinical activity identifies most individuals with alcohol dependence are admitted to acute medical assessment units (AMAUs), general medical wards (GMW) and gastro/hepatology wards (GHW) (82). We are therefore confident that there will be a large pool of eligible patients who can be approached at each participating hospital.

Each ACT has a range of methods by which patients are routinely identified or referred to their teams including, automated electronic referrals from hospital-wide screening systems (26), direct referrals (using e-referrals, phone calls) and daily ward visits to AMAU, GMW and GHW. These daily visits help identify potential referrals related to the concerns of ward staff due to the reason for admission and clinical presentation. We will use these usual routes to identify potentially eligible patients at participating ACT sites, with staff then referring patients to a research worker to complete consent and data collection. Previous studies (conducted by members of our research team) have identified that presentations for a range of reasons are associated with alcohol dependence including; mental health conditions, poisonings (including overdose), near drowning, head injury, laceration, as well as

Central Nervous System (CNS), diabetic, gastrointestinal and haematological conditions (3); alcohol withdrawal, alcohol intoxication, poisoning (paracetamol, antidepressants) chest pain and convulsions (49).

It would not be feasible to ask staff at control sites to be fully responsible for identification of patients as they will present across many clinical areas. The three control hospitals will each support and further utilise a trained research worker to identify and recruit 350 adults overall. Each recruited participant within the control hospital will be an adult admitted to hospital and experiencing alcohol dependence. The recruitment strategy will emulate that described for the ACT-hospitals. The research workers will be embedded within the Trust R&D teams and will be approved to visit appropriate wards. On a daily basis they will visit AMAU, GMW and GHW and employ a similar strategy to that of ACTs. Consent to approach individual patients will be granted by clinical staff responsible for each ward/unit and will be requested on each individual case. The same procedures for issuing participant information leaflets, allowing time to consider enrolment, and screening procedures will be adopted across all sites. With large NHS hospitals receiving more than 100,000 adult hospital admissions each year the potential pool for recruitment is more than adequate for this study.

Exclusion criteria will include those admitted <18years, not meeting the criteria for alcohol dependence, those not able to consent due to language barriers, capacity or significant cognitive impairment, those refusing to be followed-up at 6 months and those already enrolled in the study (e.g. those readmitted). Many patients are acutely unwell at the time of admission (e.g. “serious bleeds”) and so will not be approached until medically fit to be so (as per usual practice for recruitment into clinical trials in acute hospitals). Whilst some ACTs may also cover the emergency department, we will only recruit those ED attenders admitted to hospital as the control sites will lack the resources or capabilities to identify a similar cohort of ED attenders.

At baseline, researchers embedded at participating sites will recruit consenting participants during their hospital admission, collecting demographic data; age, sex, ethnicity, family composition (BFRS; (39), socio-economic status derived from Index of Multiple Deprivation (IMD) associated with patient postcode, age of first drink and age of daily drinking. Quantity and frequency of alcohol consumed over the 28 days prior to hospital admission, assessed using standard Time-Line Follow Back methods (TLFB;(40) and Alcohol Use Disorders Identification Test (AUDIT-C;41)). Presence and extent of alcohol dependence using the Severity of Alcohol Dependence Questionnaire (SADQ; (42)), alcohol-related problems (APQ; (43), quality of life (EQ-5D-5L; (44)), wellbeing (WEBWMS; (45)). Service use over the previous six- months, including alcohol specific treatment and support services will be collected using a Client Service Receipt Inventory (CSRI) specifically designed for this population, the questionnaire covers all forms of health and social care and includes contacts with the police and justice services. (46). With the exception of demographics, all data will be collected again at six-months by a researcher. Our primary outcome will be quantity of alcohol consumed in the previous 28 days at month 6, assessed in units of alcohol (where one unit equates to 10ml ethanol). The outcome battery has been used in several studies with a similar population. All the outcomes

demonstrate excellent psychometric properties in this population and take approximately 30 minutes to complete.

Over the six-month recruitment window we conservatively estimate at least 250 potential participants will be admitted to each of the six hospitals, and we aim to identify and approach 350 across the intervention hospitals and 700 across the controls, of whom we anticipate 70% will consent (46). We would expect 70% of these will be followed up at month 6 (46,47), 175 in the oACT group and 350 available for matching in the control group, from which a control sample of 175 will be matched.

Feasibility of recruitment retention and engagement

A number of trials conducted amongst individuals with alcohol dependence have been conducted in the UK, all include researchers who are part of the ProACTIVE team. They have all demonstrated feasibility of recruiting and following-up individuals with lived experience of alcohol dependence. The United Kingdom Alcohol Treatment Trial (83,84) was a pragmatic randomised trial that planned to recruit 720 individuals attending specialist alcohol treatment to test the effectiveness and cost-effectiveness of Motivational Enhancement Therapy and Social Network Behavioural Therapy employing a follow-up strategy at 3- and 12-months. This study recruited 742 participants and obtained a 93% follow-up rate at 3-months and 83% at 12-months. Similarly, a pilot randomized controlled trial (RCT) to assess the feasibility and potential efficacy of assertive community treatment (ACT) in adults with alcohol dependence (46) recruited a total of 94 high need participants who were randomized, 45 to ACT and 49 to treatment as usual. Follow-up was achieved with 98% at 6-months and 88% at 12 months.

A recent complex medicine adherence (ADAM Study – National Institute for Health and Care Research (NIHR) Award 13/86/03) randomised controlled trial to determine the efficacy of medication management with and without contingency management in comparison to treatment as usual in patients with alcohol dependence achieved the target recruitment of 748 participants and the 6-month follow-up rate of 70%. The research site which recruited participants from the ACT within an acute hospital achieved > 80% follow-up rates at 6-months. Finally, an observational follow-up study of 141 patients with alcohol dependence admitted to an acute Trust (52) obtained a follow-up rate of 94% at six months.

Together these studies demonstrate the feasibility of conducting research trials amongst this population who appear to value the opportunity to engage. Our experience has taught us that well designed and clear recruitment strategies describing follow-up procedures are essential. These involve the use of personal ‘locaters’, who are individuals nominated by the participants from within their circle of concern who can assist the research team in locating the participant should they be unable to respond to follow-up request (e.g. due to hospital admission, prison, loss of accommodation etc). However, our experience and analysis of routine administrative data also suggests that the stereotype that people with alcohol dependence seen in acute hospitals are more likely to be in transient populations is incorrect. Recent analysis of national hospital datasets for alcohol withdrawal admissions identifies only 2.7% of these individuals are recorded as being of no fixed abode (82).

Analysis: As the study is quasi-experimental participants are not randomised. To draw causal inferences of the relative effect an oACT, a counterfactual control group will be derived, using a propensity score matching approach (38). A probit regression approach will be employed, blind to group source. Known covariates that are likely to be included in the model include age, sex, quantity and frequency of alcohol use, severity of dependence and alcohol-related problems, but these may be augmented with other variables if they emerge from the initial regression analysis. Callipers of width 0.2 of the standard deviation of the width of the logit propensity score will be employed to maximise matching.

Once propensity scores have been generated, they will be incorporated into the primary and secondary analysis using inverse propensity score weights. The primary analysis will establish the mean group differences in alcohol consumed in the previous 28 days at 6 months through an analysis of covariance adjusting for key covariates including baseline consumption. Secondary outcomes will be assessed in a similar manner with the form of regression identified using diagnostic plots. The Average Treatment Effect for each group, oACT versus matched control, will be presented in terms of a marginal mean difference and 95% confidence intervals. An additional exploratory analysis will model both prognostic indicators of outcomes and any potential interactions between types of intervention delivered by the ACT and outcome observed at month six.

Our recruitment estimates are sufficient to allow for an estimation of at least a small, yet clinically important, standardised effect size difference in quantity of alcohol consumed between the group of 0.3 with 90% power and a two-sided alpha of 0.05.

7.2. WP2b: Determine the effect of ACTs on meso-level outcomes:

Rationale: The aim of this work package is to explore the impact of oACTs on hospital activity (meso level outcomes) using nationally available Hospital Episode Statistic (HES) data. Our outcomes of interest include rates of alcohol-related admissions per 100 000 population (where an alcohol-related admission is identified as alcohol-related based on established attributable fractions available in the HES dataset), associated inpatient length of stay, 30- and 90-day readmission rates after discharge from an alcohol-related admission. The 2018 PHE survey indicated approximately 60 acute hospitals may meet the inclusion criteria for being an oACT (e.g., a 7-day service staffed to deliver a range of patient and system level interventions) which will be clarified and fully defined in WP1). In our sample size simulations we have based estimates on a conservative sample of 50 hospitals.

Methods: We are interested in meso level outcomes that we hypothesise may change due to an ACT being considered ‘optimal’. Optimisation occurs at different rates in different hospitals, and dates of ‘optimisation’ will be established in WP1. The planned approach to this work package involves a quasi-experimental approach where each hospital acts as their own control, an interrupted time series (ITS). The ITS addresses the question of poor internal validity associated with simple pre- post-intervention designs by employing several pre- and post-intervention observations allowing for any underlying trends to be accounted for. Consequently, confounding becomes less of an issue particularly as there is relative stability of alcohol-related admissions over time.

We will derive data for each month over the 24-months prior to optimisation and 24-months after optimisation in each of the hospitals with an 'optimal' ACT from HES data. The data extract will include the outcomes of interest and potential covariates for adjustment. Using 24 pre- and post-intervention intervals allows for a better estimation of seasonal effects and maximises the power of statistical comparisons before and after an intervention. The number of acute hospitals included in the analysis will remain constant.

Analysis: The first step of the analysis involves visual inspection of the time series to explore changes before and after intervention. This process is enhanced with a segmented regression model to fit a least squares regression line to each segment (pre/post) of the independent variable and time, assuming a linear relationship and the outcome. This linear regression line enables an estimate of level and trend before and after the intervention, the key outcome being the difference between predicted and actual trend as the intervention is implemented in practice.

The nature and distribution of key outcomes will be assessed prior to the regression model being fitted and the model analysis will be adjusted accordingly. The analysis will allow the estimation of level and slope changes for the intervention allowing for both within and between hospital variability. Parameter estimates and associated 95% confidence intervals will be estimated using the methods proposed by Zhang (48). Where necessary the models will be adjusted for autocorrelation to avoid potential underestimation of standard errors and over estimation of p-values. To assess the fit of any models, the residuals will be examined around the predicted regression lines. The partial autocorrelation function and autocorrelation residual plots will be examined and where appropriate the Durbin-Watson test statistic derived.

The ITS will allow us to statistically assess the impact an 'optimal' ACT has on hospital activity outcomes of interest immediately and over the time, specifically: rates of index admissions per 100,000 bed-days associated with index admission and length of stay, and 30-day and 90-day readmission rates after discharge from index admission***.***
Examination of HES records indicate a 30-day readmission rate of 19% (SD 5%) for those admitted to acute hospitals with an alcohol-related condition who experience some level of alcohol withdrawal and a mean length of stay of 5.9 days (SD1.5). We conducted power calculations using a simulation approach employing the ITSPOWER module in Stata 17. We conducted simulations using three scenarios; high (0.95), high-medium (0.75) and medium (0.55) correlations between time points. Using the worst-case scenario of a medium correlation indicates the analysis has the ability to detect a minimum step change in 30-day readmission rates of 2% at 90% power and an alpha of 0.05 and a minimum change in length of stay of 0.5 at 80% power and a similar alpha, both employing a two-sided test.

7.3. WP2c: Short-term cost-effectiveness analysis of ACTs:

Methods: Following the two-stepped approach to assessing the effectiveness of oACTs taken in WP2a & 2b, a parallel costing exercise will be undertaken to assess the cost-effectiveness of both

optimal and developing ACTs in comparison to sites with no ACT provision. The first step for both analyses will be to combine data from WP1 with standard reference costs and evidence from the literature to estimate the cost of delivering 'optimal' ACTs, and the cost of delivering ACTs in the same hospitals as the service develops (in line with WP2b), as well as costs associated with alcohol treatment in the no-ACT control group from WP2a. These costs will be averaged across each Group (No ACT, 'developing' ACT and 'optimal' ACT).

For the meso- level analysis we will first analyse HES-APC data for the sites included in the WP2a analysis and use Hospital Resource Group (HRG) codes and the latest available reference costs to attach estimated costs to the NHS for each admission in the data. Second, we will use this data to undertake similar ITS analyses to WP2b, using mean cost per index admission as the outcome, to assess whether the introduction of an optimal ACT has changed the cost associated with each individual alcohol-related admission. This analysis will also indicate whether there is an underlying temporal trend in costs associated with these admissions over and above the impact of any ACTs. Third, we will combine this analysis with the outcomes of the WP2b analysis and the estimated costs of implementing ACTs to estimate the net cost impacts (on NHS costs) of fully and developing ACTs compared to the control group over the short-term (12 months).

For the micro-level analysis, we will use standard reference costs and prior estimates from the literature (including our previous STreAM modelling (33)), to attach costs to the health and specialist treatment services use recorded in the WP2a CSRI at both baseline and follow up. These costs will be pooled across all individuals within each of the three ACT /non-ACT Groups to estimate the mean pre- and post-implementation service use costs for each Group, with differences tested for significance using an approach coherent with that used in WP2a. These estimates of the service use costs will be combined with the estimated intervention costs to derive net delivery costs, after scaling up the service use costs to the total number of patients seen by each ACT (as the WP2a data will only reflect a subsample of these individuals). Finally, health-related quality of life figures, and from the WP2a data will be used to estimate the short-term cost-effectiveness in terms of costs per Quality-Adjusted Life Year (QALY) gained from optimal and developing ACTs compared to the control group.

7.4. WP2d: Modelling the long-term impact and cost-effectiveness analysis of ACTs:

Rationale: Whilst WP2c will provide a picture of the short-term cost-effectiveness of developing and optimal ACTs, the effects of ACTs may take time to be fully seen in terms of improvements in health outcomes, as well as the impact on health inequalities. The potential impact of an ACT is likely to be moderated by factors such as the prevalence of alcohol dependence, existing levels of alcohol-related harm and the distribution of these across different population groups in the local area. The Sheffield team has expertise in modelling the impacts of alcohol policy and estimates of community prevalence of alcohol dependence (33,36,37), and building on this will use the analyses of WP2a - 2c, to develop a new model to assess the potential long-term impact of ACTs from an NHS perspective.

Methods: The model (based on the simplified schematic Fig 2.) will account for individual-level characteristics, including age, sex, socioeconomic position, health-related quality of life and alcohol dependence status. Baseline healthcare usage and associated costs will be taken from a combination of external sources and WP2a-2c, as will the modifying impact of ACTs on healthcare usage and costs. Community services data will be adapted from previous work (33). Mortality rates will be taken from Office of National Statistics (ONS) published figures at the population level combined and National Drug (and Alcohol) Treatment Monitoring System (NDTMS) data for specialist community alcohol services. Micro level outcomes from WP2a (including mortality data) will integrated where appropriate.

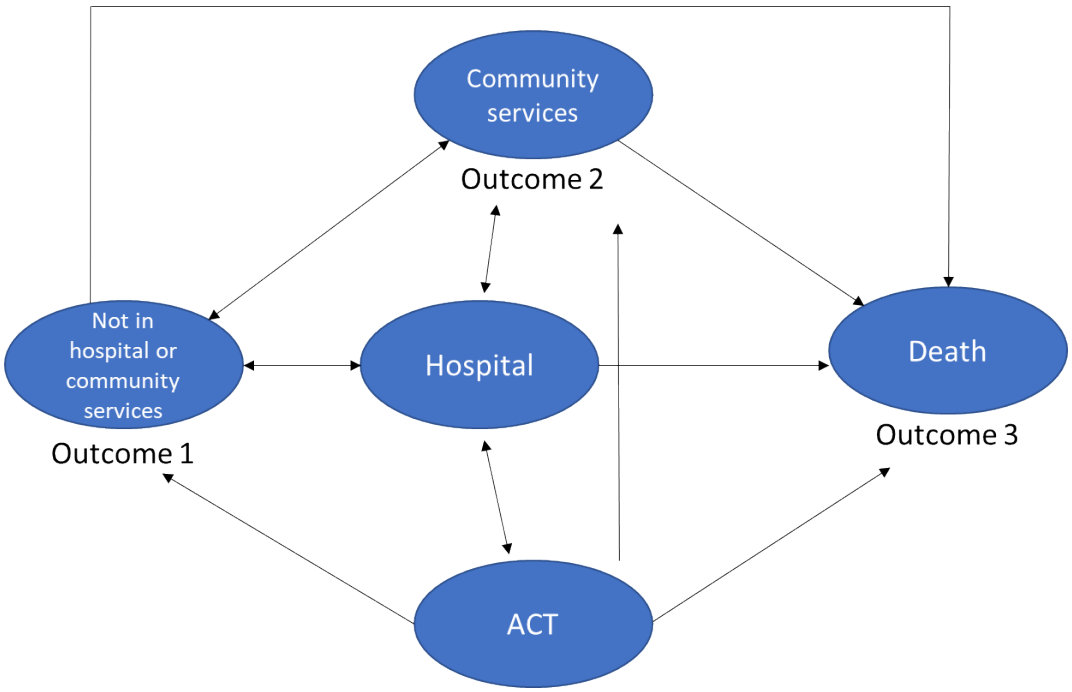


Figure 2. Schematic presentation of elements considered within ACT cost-effectiveness modelling.

The figure displays the three outcomes relating to economic costs following hospital use; not being in hospital or community services, being in community services, and death.

The model will estimate net NHS costs (including both ACT delivery costs and healthcare usage costs), healthcare service use (e.g., hospital admissions averted), community service use (e.g., successful referral into specialist alcohol treatment services) and the QALYs accrued by the modelled population over five years. It will give estimates of how health outcomes vary across socioeconomic groups, and thus the impact of introducing or optimising an ACT (or removing one) on alcohol-related health inequalities. By accounting for individual-level characteristics the aim is to capture the different groups in the wider population and how they differentially engage with services (and experience different outcomes).

Outputs from WP2:

- Characterise the cohorts of patients seen by ACTs, and the differential impact they have on patient (micro-level) outcomes and (meso-level) health service activity
- Determine the effect of different types of ACT provision on meso-level outcome
- Determine the impact level of 'optimisation' of an ACT has on rates of index admission for alcohol specific admissions, bed-days and 30- and 90-day readmission rates
- Identify the cost effectiveness of different types of ACT provision and model the net NHS costs on healthcare service use and QALYs accrued in the population of patients.

8. WP3: Qualitative Evaluation of Alcohol Care Teams

Rationale: While WP1 and WP2 will map and categorise ACTs, patients and potential/ observed outcomes, WP3 will contribute to an understanding of the reasons for variations in the composition, delivery and outcomes identified. WP3 will use an organisational ethnographic case study design (23) to derive a multi-faceted, multi-level understanding of ACT as a policy initiative (macro level), as a hospital-based liaison service (meso level) and as experienced by patients (micro level). Interventions aimed at patients with alcohol dependence are moderated by factors such as stigma (49,23), misalignment of patient and service objectives, fragmented pathways (50), and the therapeutic alliance (50,51). With one exception (52), no studies have previously focussed on how patients experience and are impacted by ACTs. There is a pressing need to ascertain how patients perceive ACTs, their goals, content, and delivery, how patients would define the optimum components and outcome measures, and to understand barriers to impact (such as stigma) from a patients' perspective.

The research questions, data collection, analysis and interpretation will be informed by the CICI framework (25), consultation with the national stakeholder network, and stakeholder input led by the PPI co-ordinator.

Methods: Organisational ethnographic case study methods (23,53) will enable triangulation of multiple data sources (documentary analysis, observation, interviews) and perspectives (decision-makers, clinical staff, patients). Four case studies will be undertaken (Fig 3). **Case Studies 1-3** will pertain to three purposively sampled ACT sites (meso/micro). Data collected in WP1 such as setting, intervention profile and context (e.g., area deprivation scores, urban/rural) will guide selection. **Case**

Study 4 will be nationwide (macro) in scope and will incorporate data from a NHSEI Prevention Team, FutureNHS (the NHSEI ACT programme online platform for all NHSEI commissioned ACTs) and the Alcohol Care Team Innovation and Optimisation Network (ACTION) a Quality improvement network set up to support the NHSEI commissioned ACTs through developing a community of practice and facilitating peer review.

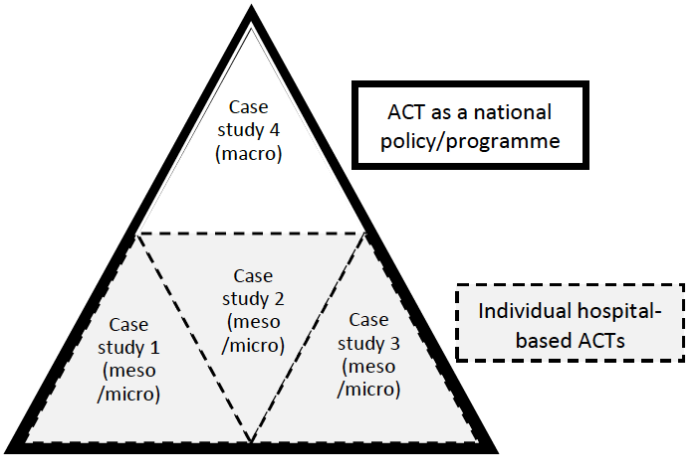


Figure 3. Schematic representation of inter-relation between case studies

Data collection: Each case study will involve three overlapping strands of data collection covering macro, meso, and micro levels. Indicative sample sizes and cases are provided but the final size and composition of the sample will be guided by the breadth and depth of data collected, its adequacy for answering the research questions and delivering the planned outputs:

Documentary analysis. A purposive sample of documents will be identified by members of the research team, WP1 survey data and WP3 interview participants. Sampling will aim to include: (i) documents produced centrally and/or with national coverage (macro); (ii) documents produced by and/or pertaining to an individual ACT including those targeted at patients but produced without patient input (meso); and, (iii) documents or parts thereof produced by or with input from patients (micro). Documents will include service descriptions, policies and guidance, training materials, mental capacity and safeguarding guidance, documentation submitted to the ACTION peer-review process, documents uploaded to https://future.nhs.uk/, inspection reports, and qualitative feedback collected via patient surveys.

Non-participant observation.
ACTION: The Alcohol Care Team Innovation and Optimisation Network (ACTION) a Quality and Accreditation network for ACTs, is commissioned by NHSEI from the Royal College of Psychiatrists Centre for Quality and Improvement as part of building a community of practice around the newly commissioned ACTs. ACTION undertakes a number of functions including a peer review process, during which ACTs have the opportunity to be reviewed by the ACTION team which includes clinicians in other ACTs as well as people with lived experience. These are all booked in advance, and so it is known who will be attending.

A convenience sample of 3-5 peer-review virtual “visits” to ACTs by ACTION (conducted on Microsoft Teams) will be observed (macro). Supplementary observation will be conducted at case study sites 1-3 with agreement from the Trust and individual site. This will involve overt non-participant observation of (for example) multi-agency alcohol strategy groups, team meetings, and associated services with a view to observing the physical setting, intra professional collaboration, staff-patient relationships and identifying unconscious bias and stigma. Observations will be recorded in the form of written or dictated fieldnotes and guided by a template featuring writing prompts to assist with organisation, analysis and comparability between researchers/sites.

Observations will be undertaken by (i) the researchers embedded in each site (as described for the WP2 prospective study), and (ii) the qualitative researcher who will visit the sites to conduct interviews with staff and patients and attend the strategy groups and team meetings. Observations will be conducted for a *minimum* of 6 months (the recruitment period for WP2) but will continue until sufficient data has been collected to answer the research questions.

Qualitative interviews. Formal (in-depth, recorded with permission) and informal interviews (impromptu exchanges during observational fieldwork) will be conducted at case study sites 1-3. Sampling will be purposive, aiming for a maximum variation sample of the three types of ‘implementation agents’ (25). Variation in the range of professions, services and patient characteristics included in the sample will not be restricted to a single site, instead we will seek variation across all sites.

- **Decision-makers (macro/meso):** Interviews will be conducted with up to 10 people involved in decisions to implement ACTs: individuals with strategic national or regional oversight, such as NHSEI, OHID, ICS (macro) and with responsibility for commissioning and monitoring ACTs e.g., the local authority, ICB (meso). Interviews with decision-makers form part of Case Study 4. Decision-makers will be identified by the research team, stakeholders, and via consultation of publicly available documentation. The team and stakeholders will review the resulting sample for gaps and suggest further participants if required.

- **Staff (meso/micro):** We will aim for a sample of 12-18 people involved in implementing or delivering ACTs, i.e., ACT clinicians as well as other staff from services set out in the ‘pathway for alcohol dependent patients’ (10) including psychiatric liaison, and local community mental health and addiction services. At minimum, interviews will be sought with the clinical lead and a specialist nurse from the Alcohol Care Team and a minimum of two professionals outside the team. Interviews with staff form part of Case Studies 1-3. It will be possible to identify some staff (i.e. clinical lead and specialist nurse) involved in implementing or delivering ACTs at sites 1-3 (site selection described above) using the data retrieved in the WP1 survey. Voluntary informed consent will be sought from these individuals in the first instance. Further staff connected with ACTs in these sites will be identified and recruited via snowball and convenience sampling involving recommendations and introductions from the initial participants at each site. Identification of further potential participants will be possible due to observation in clinics and meetings. ACTs

comprise multi-disciplinary teams thus providing an extensive pool of different professions from which we can recruit our sample.

- **Patients (micro):** We will aim for a sample of 20-30 people, sampled to reflect the diversity of clinical populations seen by ACTs, including variation by severity of alcohol dependence, complexity/multimorbidity, status (e.g., high intensity service users, and those new to treatment), number and length of stays, ensuring representation of underserved groups (21). Where required, reasonable adjustments will be made to enable the invitation and participation of individuals with potential barriers to their participation, such as language, literacy, sensory disabilities, digital access etc. However, patients aged under 18 or who do not have the capacity to provide informed consent to participate will be excluded. Patients will be identified and invited to participate during their hospital admission. They will be identified using the same methods as specified for participation in the prospective study (WP2). The embedded researcher collecting baseline data for the prospective study will also provide information about the qualitative study and seek permission for follow-up by the qualitative researcher. The qualitative researcher will seek voluntary informed consent and arrange an appointment time prior to the patient's discharge from hospital. Interviews will be conducted post-discharge according to the participant's preferences (face-to-face, telephone, video), subject to confirmation of informed consent.

All interviews will explore participants' experiences and views of ACTs, from their respective perspectives. All participants will be asked to identify barriers and facilitators to implementation and optimisation, what the impact has been, and what they need to make ACTs work from their perspective/for them. These broad topics will be tailored for each participant group, for example, decision-makers will be asked to identify barriers to funding/commissioning ACTs, staff will be asked about barriers to delivery, and patients asked about barriers to, and acceptability of ACT provision.

Patients will be recruited during their hospital admission but interviewed post-discharge. A hybrid approach to fieldwork will facilitate ease of participation and flexibility in the event of pandemic-related visiting restrictions to hospitals. Accordingly, provisions will be made for face-to-face or telephone/video interviews. All interviews will be digitally-recorded using encrypted devices. For transparency, decision-making will be recorded and due consideration given to the impact of the method of data collection on the data and subsequent findings.

Analysis. NVivo qualitative analysis software will be used to store, manage and code all documents, fieldnotes and transcripts. An inductive thematic analysis (54) including all sources will be undertaken and data will also be coded deductively using tools developed as part of the CICI framework (25). Analysis will pay specific attention will be paid to the ways in which different intervention agents define optimisation, core components, impact and outcomes and the extent to which these align. 'Pen portraits' (24) will be developed to facilitate the integration of large amounts of different types of data and potentially conflicting insights from different implementation agent perspectives. At least four pen portraits (one per case study) will be produced and populated with key messages distilled from the thematic analysis. An implementation and impact profile will be produced for each case study

(including Case Study 4 of ACTs as a national policy/programme), identifying its main characteristics and key influences on these. This method will facilitate both 'within case' analyses (i.e., comparing different data sources and different perspectives) and 'cross case' analyses (i.e. comparing different settings and context) and will be used to determine both meta and site-specific influential factors. A template has been designed to guide the population of the pen portraits, though this will be further developed iteratively during the fieldwork and analysis.

Permissions. Agreement in principle has been obtained from the ACTION team for analysis of documentation submitted to the ACTION peer-review process and observation of visits. Formal approval will be sought as part of an overarching application made via IRAS (see below) for data collection with ACTION, access to documents uploaded to https://future.nhs.uk/ (other documents are in the public domain), observation conducted at case study sites 1-3 and the identification, recruitment and interviewing of potential participants. Our application for approval will specify that individual consent will also be sought where appropriate. For example, patients' consent to the WP1 survey will cover analysis of their qualitative feedback in WP3; verbal agreement will be sought from attendees at observed meetings and involved in virtual "visits" by ACTION.

PPI input to WP3. The integrated PPI team (consisting of PPI co-ordinator (MK) researchers (KC, SU) and CI (JS) has influenced the development of WP3 by ensuring the patient voice is privileged and shaping the thrust of the enquiry via a critical approach to the notion of an "optimised" ACT, by asking "optimised for whom?" Throughout the development and delivery of WP3, the integrated PPI team will meet regularly to identify the specific roles and tasks that would benefit from stakeholder input and to identify how best to undertake these. Examples might include reviewing the sample characteristics to identify gaps, suggesting areas of focus for the fieldwork (observational and interviews), reviewing any project-related literature to ensure the use of appropriate and non-stigmatising language (and generally alerting the team to unconscious bias), and interrogating our analytic and interpretive processes during analysis and the interpretation of findings.

Outputs from WP3

- Summary of barriers and facilitators to the operationalisation and delivery of ACTs, what implementation agents may require to overcome the barriers, as well as the lessons learnt
- Summary of documents available to support and guide ACTs
- Summary of patients' reasoning around uptake, hidden barriers, (e.g., stigma), patient and carer defined 'impact' and 'outcomes'
- Contribute to development of guiding principles toolkit for the delivery of what might constitute a truly 'optimal' ACT

9. WP4: Data integration, dissemination and recommendations for future policy and practice

Rationale: Three critical considerations shape the design and focus of WP4:

1. Phased implementation of 'optimal' ACTs in England will take place as part of the LTP, over the course of the evaluation, providing formative as well as summative learning and dissemination opportunities. This vertical work package is designed to ensure timely sharing of emergent messages with policy makers and clinicians to maximise impact (55).
2. ACTs are a prime example of a complex intervention implemented in a complex adaptive system (22,25). We will draw on the CICI Framework (25) to shape the organisation and integration of evaluation data and to better understand interactions between the intervention (ACTs), their implementation, delivery setting and wider context.
3. Recognition of the added value (quality, relevance, uptake) and social justice in involving wider stakeholders in the production and dissemination of knowledge of ACTs (56), WP4 activities will be underpinned by continuous engagement with key evaluation stakeholders, including policy makers, clinicians, patients and the commissioners.

Methods:

Interim policy briefs and lay summaries. At pre-specified timepoints, initial findings from each WP will be reviewed, integrated, and disseminated (see outputs 1a-f below). Members of WP teams will work together to discuss implications from emergent data, produce descriptive overviews of key messages, with any immediate implications for policy or practice. These drafts will be shared with the ACT Stakeholder Network and PAG members for feedback, and subsequently refined into interim policy briefs and plain English summaries following best practice guidelines in terms of structure, style, and content (55). Briefs/summaries will be disseminated using existing policy, practice and academic networks, with which the research team are well integrated, as well as via appropriate social media outlets, websites, and webinars.

Evaluation toolkit and recommendations. The final phase will comprise an in-depth review and synthesis of evidence gathered during the project, reflecting on a series of CICI-informed questions (25) to consider how the setting, context and process of implementation have shaped the content, experience, and outcomes of ACTs over time. For example:

- Focussing on the *intervention* itself, we will examine how 'optimal' ACTs have been defined, understood, and applied to date, and test them against data from this evaluation
- In relation to *context*, we will examine which aspects of the wider social, political, and economic context have affected implementation of optimised ACTs, and how these factors have interacted.
- For *setting*, we will explore how the definition and application of optimised ACTs has varied between different delivery settings.
- For *implementation*, we will identify: which processes, strategies and delivery agents have been used to implement ACTs, including common or site-specific barriers and facilitators; how different stakeholder groups (patients, providers and policy makers) have understood and experienced

ACTs; and what impact different configurations and implementation processes of ACTs appear to have had on individual and system level outcomes of interest.

These questions will inform the production of two final overarching outputs:

1. A comprehensive implementation toolkit specifying guiding principles for effective and sustainable ACT commissioning and delivery. Toolkit sections will cover: a) introduction to ACTs and evidence of impact (effectiveness and cost-effectiveness); b) design and scope of ACTs (taxonomy of components and models of care); c) understanding the delivery context (site-specific factors, population/community factors, local/national policies and guidelines); d) implementation barriers/facilitators and evidence-based strategies for sustained delivery (focussed at meso (health system) and micro (patient and provider) level (57).
2. Recommendations for future policy and practice including resource, training, and research needs. Recommendations will be shaped using APEASE criteria (Acceptability, Practicability, Effectiveness, Affordability, Side-effects and Equity) as appropriate (58).

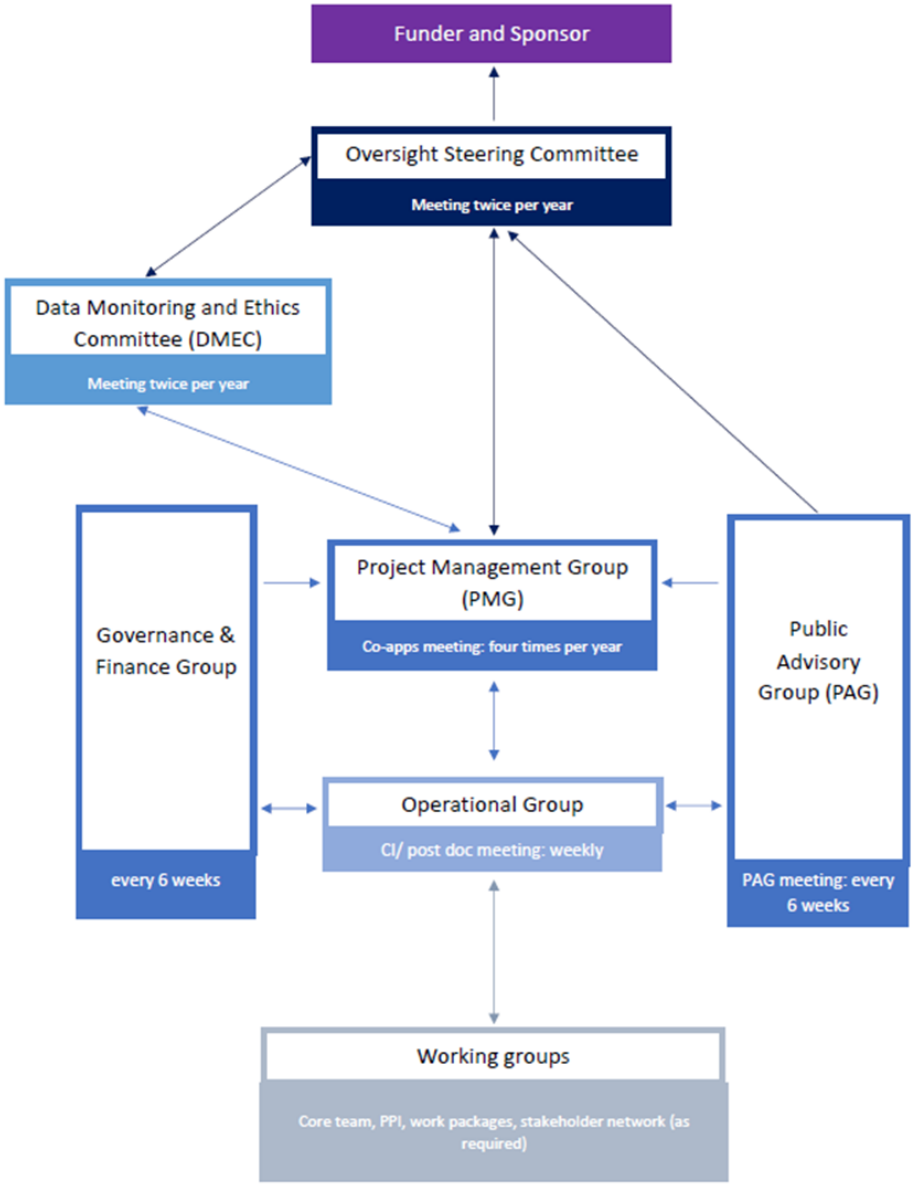
Outputs from WP4:

1. Policy briefs and lay summaries of key WP findings:
    a. Comprehensive national map of ACT provision
    b. Overview of the essential components needed for an effective ACT from a range of perspectives
    c. Overview of implementation barriers and facilitators
    d. Overview of characteristics and cohorts of patients who may benefit most from ACTs
    e. Patient views and experiences of ACTs
    f. ACT impact on micro level cost, health outcomes and inequalities
2. Implementation toolkit specifying guiding principles for effective and sustainable ACT commissioning and delivery
3. Recommendations for future policy and practice including resource, training, and research needs

10. Summary of patients/ carers/ public as research collaborators

A structure for pro-active co-production has been designed to underpin engagement with a wide range of stakeholders throughout all phases of the study. There are three pillars to this structure: 1) a Public Co-applicant; 2) a PPI co-ordinator; and 3) an actively engaged network of Stakeholders. The Public Co-applicant and PPI co-ordinator are an integrated part of the programme team, and from the outset will contribute to the development of the programme. Central to this is the development of a full PPI strategy (termed a 'PPI Approach' for this programme of research), led by the integrated PPI team with contributions from other Co-applicants and researchers on the project. This strategy ensures that each element of the research embraces co-design and incorporates the views of stakeholders, particularly those with lived experience. In addition, the project will focus on the development of a stakeholder network to be sustained beyond the life of the project. The PPI team input will target unconscious bias, assumptions, and potential stigma in the enquiry, interpretation of results and outputs. This elevates the patients' perspective by asking 'optimal for whom?' and challenging taken-for-granted service-oriented definitions of outcome measures. The current version

of the PPI Approach can be found in



ProACTIVE Reporting Structure, Version 2, 17/Mar/2023

Appendix 3.

The research team has significant expertise in enabling people with alcohol dependence and marginalised groups to be engaged in research studies and proposed data collection methods in WP2a and WP3 reflects this.

11. Project Management and Data Quality Assurance

This is a complex study delivered by a geographically dispersed consortium which harnesses the expertise of a range of experienced researchers. A key aim of the application is to grow regional research expertise bringing together methodological and alcohol specific expertise to best identify and include underserved groups in this under-researched area. The project is therefore co-led between University of Southampton (responsible for overall delivery and management of the project) and University of Hull, (responsible for data management, governance and quality assurance across all work packages).

The governance structures are shown in the ProACTIVE study timeline (Fig 4), and consist of the following:

- An independent Oversight Steering Committee, chaired by Professor Sir Ian Gilmore. This will meet approximately every six months to give independent oversight to the project. It is anticipated that five of these will be virtual and one face-to-face (f2f).
- Project Management Group (PMG), chaired by the joint CIs. This will occur every three months and involve all co-applicants and collaborators, as well as research staff (where applicable for project stage). It will support the development and design of project elements and oversee the delivery of projects against key milestones. The programme is divided into four work packages with WP1 and WP2 predominantly utilising quantitative methods, with WP3 and WP4 utilising qualitative and mixed methodological approaches. The simultaneous development and delivery of these elements requires complimentary project management skills and therefore have identified the need to recruit two postdoctoral researchers who will work closely with the HHTU, and PPI Co-ordinator to ensure the coordinated effective delivery of the programme of research, under the direction of the CIs and PMG. It is anticipated that there will be three face-to-face meetings (during each integration and implementation strand) but the rest will be held virtually. Meetings

will be held in a non-commercial venue in London to reduce travel and accommodation costs.

- Governance and finance Group, chaired by Hull CTU lead (JC). This will occur virtually every six-weeks and ensure approvals, agreements and reports are all in place, and budget reconciliation to oversee project spend across work packages and sites. One or both CIs (JS/ TP) will aim to attend each meeting.
- Weekly operational meeting, co-ordinated by post-doctoral researchers, employed on the project to ensure each project remains on tract, supervise research and administrative staff, and invite other team members (as required) for the operational needs of the project. One or both CIs (JS/ TP) and postdoctoral researchers will aim to attend each meeting.

A diagram of the ProACTIVE reporting structure is included in Appendix 2.

12. Ethical and Regulatory Approvals

Access, purchase, and approvals to nationally available datasets will be overseen by HHTU.

Three submissions for NHS ethical review are planned (to align with Schedule of Events Cost Attribution Template (SoECAT) forms 1 and 2).

- Ethical review application 1: . For WP1, to include survey (WP1a), Delphi process (WP1b), access to routine data sets (where required), and part of work of WP3.
- Ethical review application 2: For WP2a, prospective study at 6 sites, recruiting patients, consent to follow-up, access to patient electronic record. WP3, qualitative interviews with patients, carers, and staff. Public Contributor network will assist in the co-production of research processes for ensuring inclusivity, informed consent, maximising follow-up rates and input into follow-up measures and topic guides.
- Ethical review application 3: DARS application to NHS Digital.

13. Dissemination, outputs and anticipated impact

As outlined in the PPI section and WP1, there is a clear process from the outset of the project to develop a national ACT Public Contributor network and actively engage with it. The structure of regular meetings run by the PPI co-ordinator will ensure that a wide range of stakeholders, including a regular Patient Advisory Group are involved throughout in the co-production of the research processes and synthesis of findings. By implication this is a central part of the dissemination strategy (WP4), rather than being a separate exercise.

Agreement around collaboration has already been sought and agreed from the following organisations and networks:

- NHSEI National Prevention Team
- OHID Alcohol Team
- NHSEI Regional Prevention teams
- NIHR Applied Research Collaborations (specifically with the national priority consortia on Prevention, Health Inequalities and Mental Health)
- Alcohol Care Team Innovation and Optimisation Network (ACTION)
- Royal College of Psychiatrists
- British Society for Gastroenterology

Key outputs from the project are listed at the end of the description of each WP and will be synthesised as part of WP4.

Interim outputs within this 36-month project include:

- An active, engaged national ACT stakeholders' network to support the development and implementation of ACTs
- Comprehensive national map of ACT provision; variation in models, scope and commissioning

- Overview of the essential components needed for an effective ACT from a range of perspectives
- Overview of meso-level barriers and facilitators for ACT implementation
- Overview of characteristics and cohorts of patients who may benefit most from ACTs
- Patient views and experiences of ACTs
- ACT impact on micro level cost, health outcomes and inequalities
- Implementation toolkit specifying guiding principles for effective and sustainable ACT commissioning and delivery
- Recommendations for future policy and practice including resource, training, and research needs.

In addition, full results will be published in academic journals and conferences to enhance the evidence base to inform policy and practice. This includes the characterisation of cohorts of patients seen by ACTs, and the differential impact on individual outcomes and health service activity; cost effectiveness of different models of ACTs and the QALYs accrued in the population of patients, an understanding of the patient experience of ACTs. Given the paucity of evidence on ACTs to date, these will form the basis for any future clinical guidelines.

In the short term the most tangible impact from this project will be the ability for policy makers to make evidence-based decisions on the clinical and cost-effectiveness of ACTs, where and how they work best and in which group of patients. It will amplify the voices of people with lived experience of alcohol-related problems and of ACTs, throwing light on the role of shame and stigma in alcohol services, and the implications for health inequalities. The project will develop a new consortium bringing together methodological and alcohol specific expertise to best identify and include underserved groups in this under-researched area developing appropriate research methods and enhancing recruitment to the NIHR portfolio under Mental Health (Addictions).

In the longer term, the results of this project, by clarifying the characteristics and cohorts of ACT patients, providing a taxonomy of care components delivered, and defining how best to measure outcomes will enable multi-centred research on which psychological and pharmacological interventions are most effective. It is hoped that the results will assist in the training of non-specialist staff in acute hospitals as well as developing the competencies of ACT staff to improve outcomes for patients.

A key barrier to implementation of findings and further research is the lack of a national patient voice in this area of health policy and practice. Development and maintenance of a national PPI group would be the first in this area and could help remove some of the stigma towards people with alcohol dependence admitted to acute hospitals that reinforce those views.

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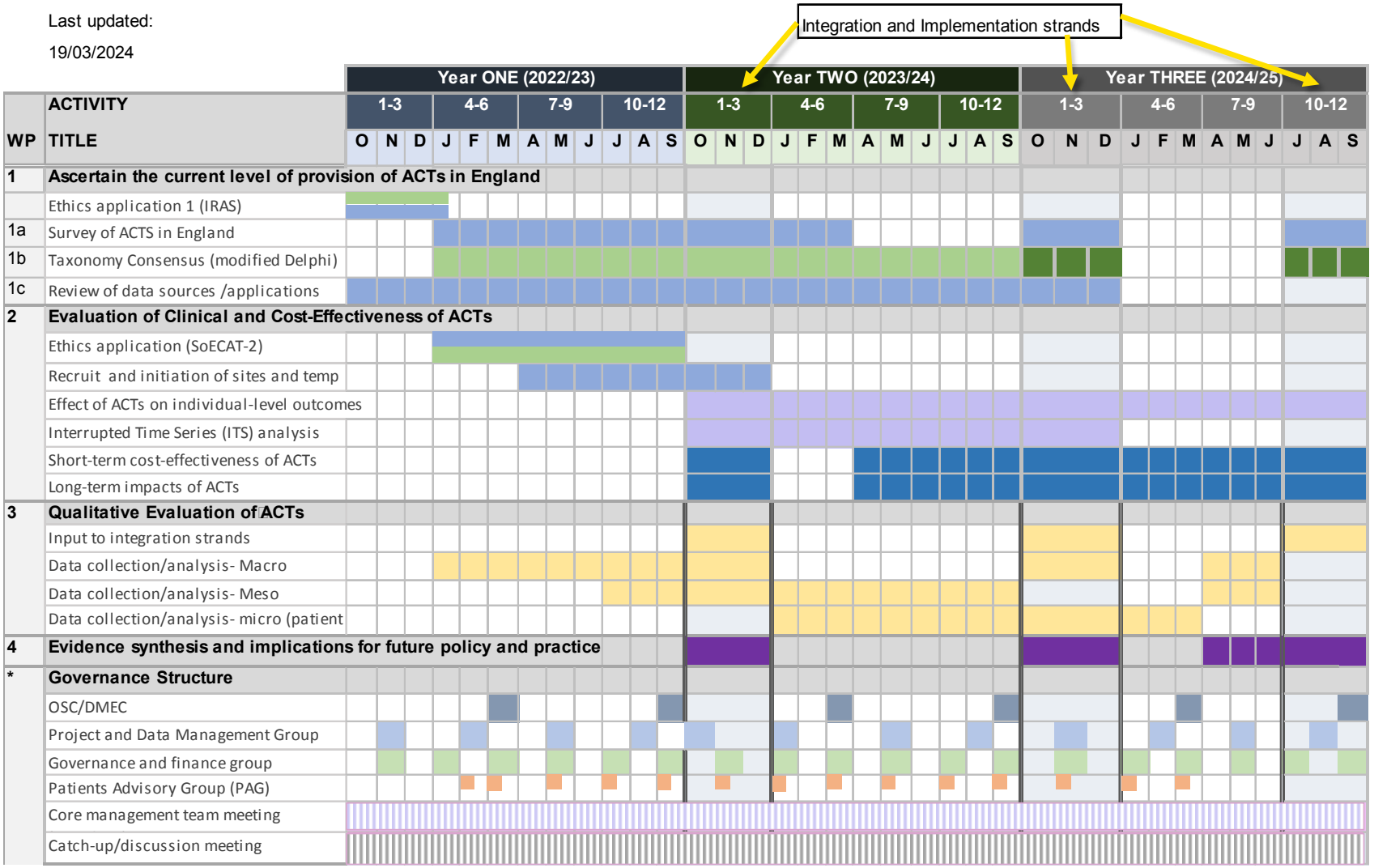
15. Appendices

Appendix 1 – Gantt chart

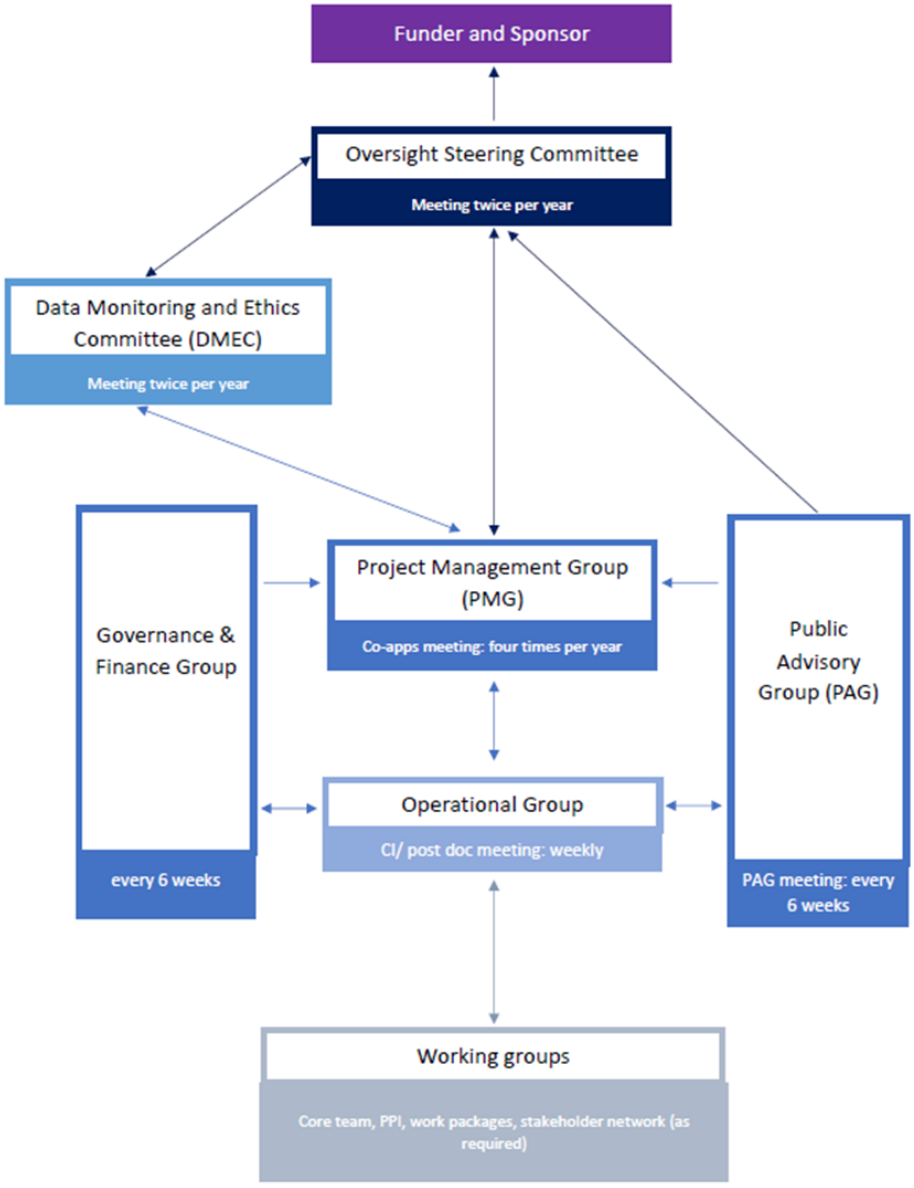
Timeline-Programme of research for Alcohol Care Teams (ACTs): Implact, Value and Effectiveness (ProACTIVE)

Last updated:

19/03/2024

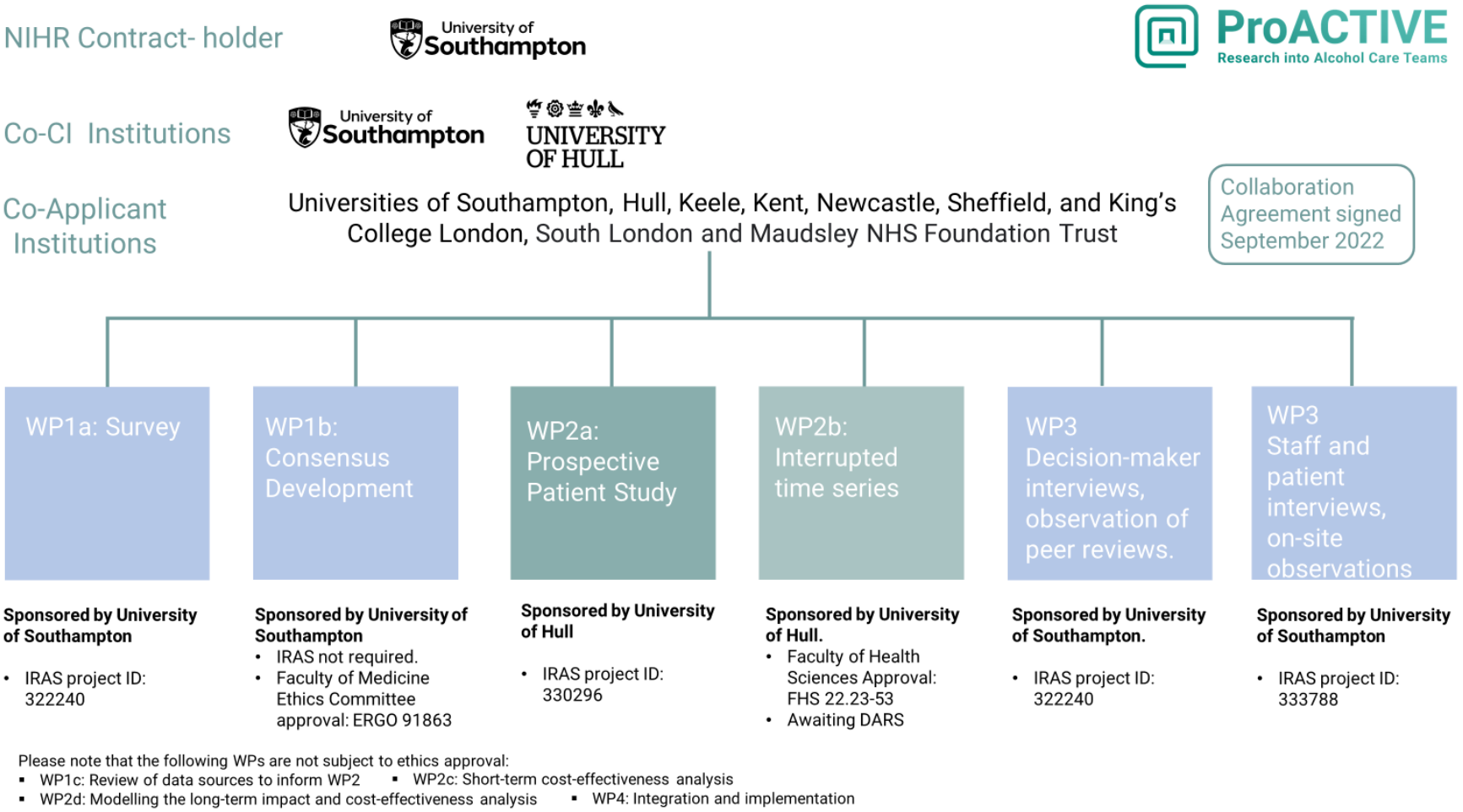


Appendix 2 – ProACTIVE reporting Structure



ProACTIVE Reporting Structure, Version 2, 17/Mar/2023

Appendix 3 – Work packages, ethics approvals and sponsorships



Please note that the following WPs are not subject to ethics approval:

- WP1c: Review of data sources to inform WP2
- WP2c: Short-term cost-effectiveness analysis
- WP2d: Modelling the long-term impact and cost-effectiveness analysis
- WP4: Integration and implementation

Appendix 4 – WP1a + protocol

IRAS approved WP1a+ protocol V

*Double Click the icon on the right to access full protocol.

FULL PROTOCOL TITLE	**Programme of research for Alcohol Care Teams: Implementation, Value and Effect (ProACTIVE): Understanding the Provision in Acute Care in Hospitals Nationally (WP1a+)**
Short title	ProACTIVE National Survey of Hospital-based Provision of Alcohol Care in England
Protocol version	Version 1.0 27th February 2023
HHTU REFERENCE NUMBER	
REC REFERENCE NUMBER	23/HRA/0311
IRAS PROJECT ID	322240
ISRCTN REFERENCE NUMBER	
CHIEF INVESTIGATORS	Prof Thomas Phillips, Professor of Nursing (Addictions) (Co-Chief Investigator and point of contact), Institute for Clinical and Applied Health Research (ICAHR), Allam Medical Building, University of Hull Hull, HU6 7RX, UK thomas.phillips@hull.ac.uk 0734 166 1968 Prof Julia Sinclair, Professor of Addiction Psychiatry (Co-Chief Investigator and point of contact), Clinical and Experimental Sciences Faculty of Medicine University of Southampton Julia.sinclair@soton.ac.uk
CHIEF INVESTIGATORS	 Prof Thomas Phillips Prof Julia Sinclair
DATE	22/12/22

Appendix 5 – WP1b protocol

*Double Click the icon on the right to access full protocol.

ProACTIVE Final Phase of WP1b Pro

FULL PROTOCOL TITLE	Programme of Research into Alcohol Care Teams: Impact, Value and Effectiveness (ProACTIVE) WP1b: Establishing a consensus for the essential ACT components of delivered care
SHORT TITLE	ProACTIVE WP1b: Establishing a consensus for essential ACT components
PROTOCOL VERSION	Version 1.1
ERGO REFERENCE NUMBER	91863
CHIEF INVESTIGATOR	Prof Julia Sinclair, Professor of Addiction Psychiatry Faculty of Medicine, University of Southampton College Keep, Terminus Terrace, Southampton, SO14 3DT UK julia.sinclair@soton.ac.uk 8231 0764
CHIEF INVESTIGATOR	Signature 
DATE	27/02/2024

Appendix 6 – WP2a protocol

ProACTIVE WP2a
Prospective Patient

*Double Click the icon on the right to access full protocol.

UNIVERSITY OF HULL

University of Southampton

ProACTIVE
Research into Alcohol Care Teams

FULL PROTOCOL TITLE:

Prospective pragmatic quasi-experimental study to assess the impact and effectiveness of alcohol care teams (ACTs) targeting adults with alcohol dependence admitted to NHS Hospitals in England: the ProACTIVE prospective patient study protocol

SHORT STUDY TITLE:

The ProACTIVE Prospective Patient Study

Protocol version number and date: Version 1.1, 14/Nov/2023

IRAS Number:

330296

ISRCTN Number:

ISRCTN10723141

Sponsor Number:

RS201

Funder Number:

NIHR152084

Appendix 7 – WP3 (patient, staff interviews and site observation) protocol

*Double Click the icon on the right to access full protocol.

ProACTIVE WP3b_Study_Proto

FULL PROTOCOL TITLE	**Programme of research for Alcohol Care Teams: Impact, Value and Effectiveness (ProACTIVE)** - Qualitative Investigation of Prospective Patient Study of Alcohol Care Teams (WP3b)
SHORT TITLE	ProACTIVE - Qualitative Investigation of Prospective Patient Study
PROTOCOL VERSION	Version 1.1 12th December 2023
REC REFERENCE NUMBER	
CHIEF INVESTIGATOR	Professor Julia Sinclair
WORK PACKAGE LEAD	Dr Krysia Canvin Research Fellow in Involvement and Engagement NIHR Three Schools' Mental Health Research Programme University of Keele
SIGNATURE	
DATE	12/Dec/2023