Crafting a case-finder of traumatic brain injury for patients and staff in community drug and alcohol treatment

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Statement of authorship

The candidate confirms that the work submitted is his own and that appropriate credit has been given where reference has been made to the work of others.

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Dedications

I dedicate this to my partner Katy for the late nights and lost weekends. I couldn't have done this without you. And to my son, Alexander, for his love, support and encouragement.

Abstract

Purpose: To develop a user interface with embedded clinical decision support software for detecting self or proxy reports of lifetime exposure to TBI with patients receiving community drug and alcohol treatment.

Method: Human centred design standard was adopted in the adaptation of the Ohio State University Traumatic Brain Injury Identification Method. A prototype head injury survey user interface was developed following usability design guidelines with stakeholder involvement. The initial instrument design underwent formative usability evaluation using cognitive walkthrough with a concurrent embedded mixed methods design. Four patients and four staff from a community drug and alcohol treatment service were purposively recruited for usability testing.

Results: A thematic analysis was conducted and three themes were identified; user interface problems and improvements, living with TBI, and high tech or low tech healthcare. The theme user interface problems and improvements was quantified using problem discovery analysis to prioritise the five pre-defined user interface categories; navigation, content, page layout, terminology, data entry and technology for redesign (Rubin, 1996). Patients' highest redesign priority was navigation and for staff it was data entry and technology.

Design recommendations: The prototype head injury survey application had ten user interface design recommendations. The next design iteration will be sensitive to neurological deficits, limited IT skills and low reading ability. Several implications for practice in conducting TBI screening were identified. Staff should retain control over the administration of the head injury survey application as the recollection of past traumatic events was distressing for patients. Family and friends should be involved in TBI screening to help differentiate any changes in neurological functioning post head injury. Administration of the instrument should be restricted. Preferred delivery method was clinical interview using mobile computer technology. Electronic healthcare records could provide prompts to conduct TBI screening if associated clinical markers for head trauma have been detected.

Abbreviations

ACRM – American Congress of Rehabilitation Medicine

API – Application programming interface

BISI – Brain Injury Screening Index

BISF – Brain Injury Screening Form

BISQ – Brain Injury Screening Questionnaire

BTS – Brief TBI Screening

CDC – Centres for Disease Control and Prevention

CDSS – Clinical decision support software

CT – Computed tomography

DTI – Diffusion tensor imaging

EC – European Commission

GCS – Glasgow Coma Scale

HRSA – Health Resources and Services Administration

IHISI – Iowa Head Injury Screening Instrument

ISO – International Organization for Standardization

MHRA - Medicines and Healthcare products Regulatory Agency

NICE – National Institute for Health and Care Excellence

NHS – National Health Service

NIHR – National Institute for Healthcare Research

OSU TBI-ID – Ohio State University Traumatic Brain Injury Identification Method

PC – Personal computer

PET – Positron emission tomography

PPI – Patient and public involvement

STDDT – Screening Tool for Dual Diagnosis and TBI

TC – Tablet computer

TBI – Traumatic brain injury

TOP – Treatment outcome profile

TSTS – TBI Screening Tip Sheet

UEM – Usability evaluation methods

WHO – World Health Organisation

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1.0 Introduction

This thesis explores the use of mobile health application technology for detecting traumatic brain injury (TBI) in patients receiving community drug and alcohol treatment. The structure of this thesis is as follows. Chapter 1, outlines the aims and objectives of the study and introduces human centred design as a standard for health application development. Chapter 2, provides the rationale for routine TBI screening for patients receiving community drug and alcohol treatment using health application technology. In chapter 3, a scoping review was conducted to identify validated case finding instruments for detecting lifetime exposure to TBI. The instruments were reviewed and the rationale offered for the use of heath application with embedded clinical decision support software. Chapter 4, details the pragmatic methodological underpinnings for the development of mobile health applications. Chapter 5, describes the usability design and evaluation methods from stakeholder involvement to formative usability testing. Chapter 6, presents the findings from the formative usability evaluation of a prototype health application with patients and staff in a community drug and alcohol treatment setting. Chapter 7, integrates and synthesises the formative usability findings with the wider literature and provides a discussion of the implications for policy and practice with limitations of the study. Chapter 8, concludes with the key findings of the study from the application of human centred design and evaluation in healthcare including recommendations for future research.

1.1 Aim

The aim of this study was to develop a user interface with embedded clinical decision support software for detecting self or proxy reports of lifetime exposure to traumatic brain injury (TBI) with patients receiving community drug and alcohol treatment.

1.2 Objectives

- To review the available literature and identify a case finder for detecting self or proxy reports of lifetime exposure to TBI for patients receiving community drug and alcohol treatment.

- To develop a user interface adapted from a standardised case finder for detecting self or proxy reports of lifetime exposure to TBI with stakeholder involvement following usability design guidelines.
- To conduct a formative usability evaluation of the prototype user interface for a TBI case finder with patients and staff in a community drug and alcohol treatment service through the identification of usability problems and idea generation for redesign.

1.3 Medical device standalone software regulation in Europe

Health applications are becoming increasingly predominant within health and social care (NHS Innovations South East, 2014). Health applications can have multiple functions including diagnosis, therapy and monitoring (NHS Innovations South East, 2014). Health applications must demonstrate compliance to European directives (MHRA, 2016). There are four classifications of medical device and the UK Medicines and Healthcare Products Regulatory Agency (MHRA) provide guidance in how to classify a health application (MHRA, 2016). Understanding the regulatory pathways for medical device classification is essential when marketing the health application in Europe (MHRA, 2016). The classification system supports the development team in determining whether the health application would be considered a medical device (MHRA, 2016).

1.3.1 Navigating the regulation

The primary function of EU regulation for standalone software is to provide a framework for market access, international trade and regulatory convergence (Altenstetter, 2012). The regulation promotes patient safety, innovation and market competition (Carroll and Richardson, 2016). The MHRA have published guidance in how to navigate European directives, ensuring the medical device is compliant with regulations (MHRA, 2016). Medical devices in Europe are regulated by three European directives:

- 93/42/EEC amendments 2007/47/EC concerning medical devices
- 90/385/EEC concerning active implantable medical devices
- 98/79/EEC concerning in vitro diagnostic medical devices

  (MHRA, 2016)

Standalone software can either be a medical device or an accessory (McHugh et al., 2011). MEDDEV 2.1/6 provides specific guidance in the qualification and classification of standalone software including mobile health applications (EC, 1993).

1.3.2 Definitions

To determine whether a health application is a medical device it needs to meet the following definition:

> '… any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
> - investigation, replacement or modification of the anatomy or of a physiological process,
> - control of conception,
>
> and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function'
>
> EC (1993) pg.5

Standalone software has been defined as:

> '… software which is not incorporated in a medical device at the time of its placing on the market or its making available'
>
> EC (1993) pg.7

A health application for detecting lifetime exposure to TBI could meet the provided definitions in the following way. The application is diagnostic software for detecting brain injury in patients caused by head trauma and is not incorporated into a medical device.

1.3.3 Classification

To determine the appropriate regulatory pathway the health application must follow, the classification of the device must first be established (MHRA, 2016). Medical device classification is a risk focused system accounting for vulnerability of the human body and associated risks with the devices (MHRA, 2016).

Prior to classification standalone software must meet the following criteria:

- Computer program
- Not incorporated into a medical device
- Perform activities different to storage, archive or search
- Provide an action for patient benefit
- Meet the definition of a medical device or an accessory
  (EC, 1993)

Standalone software which has met the definitions of a medical device is subject to classification criteria found in Annex IX of Directive 93/42/EEC which can be found in appendix A (EC, 1993). In this study classification rule 1 (EC, 1993) applies, as it is a non-invasive device.

This designates the health application as a class I medical device (EC, 1993). The health application can further be compartmentalised into modules (Boccardo et al., 2014). The intended use of the modules determines whether they have a medical purpose (Boccardo et al., 2014). In this study, modules of the health application which provided information advice and guidance in relation to TBI or instruction in how to make a referral to specialist brain injury services may be considered non-medical device modules and not subject to regulation for medical devices.

1.3.4 Conformity assessment route for CE marking

Health applications cannot be marketed for use with a CE mark until they have undergone a conformity assessment (MHRA, 2016). The designated CE mark is based on the classification of the medical device (MHRA, 2016).

In early instrument design and development consideration must be given to regulatory requirements (HRSA, 2006). The area of regulation prioritised in this study focused on the ergonomics of human-system interaction.

> 'This shall include:
>
> - reducing as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety) and
> - consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users (design for lay, professional, disabled or other users)'
>
> MHRA (2016) pg.27

1.4 Human centred design and evaluation

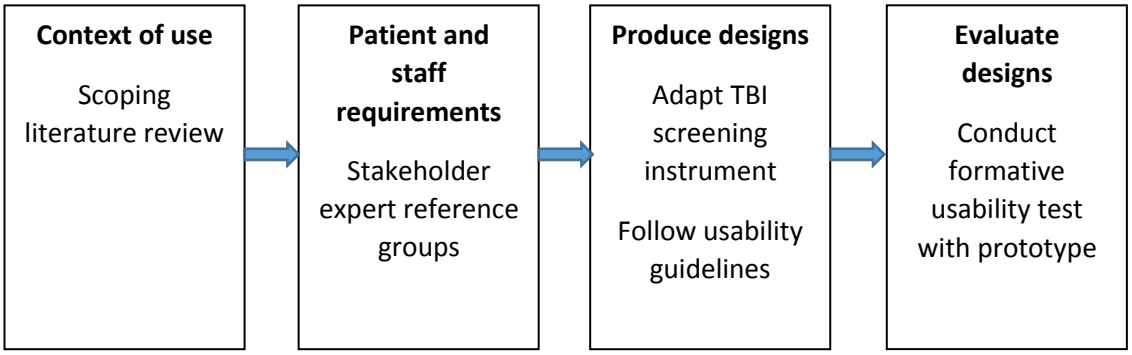
Williams (2012) report highlighted the need to conduct routine TBI screening with at risk patient groups. Patients receiving drug and alcohol treatment are at risk of TBI (Silver et al., 1997). Detecting TBI in patients with co-occurring substance use disorder and neurological disability is complex (American Psychiatric Association, 2013, Iverson et al., 2005). Developing health application technology with embedded clinical decision support software for detecting TBI was considered to be a viable solution by the research team in this study. Human centred design provides a framework to develop an instrument which is simple to use through revealing the unique requirements of the end user and other stakeholders (ISO, 2010).

The ergonomics of human-system interaction standard (ISO, 2010) offered broad guidance in the planning and management of usability research. The guidance did not extend to choice of paradigmatic approach or specific instruction in what usability methods and techniques should be incorporated into the study. Chapter 4, provides an explanation for the use of a pragmatic methodology and the incorporation of a concurrent mixed methods research design.

Human centred design had four development phases; 1) understand and specify the context of use, 2) specify the patient and staff requirements, 3) produce design solutions, 4) evaluate design solutions (ISO, 2010).

Figure 1 provides a broad overview of the adoption of the human centred design and evaluation process for this study, and is expanded upon in this chapter.

Figure 1 - User centred design and evaluation process



1.4.1 Context of use

A scoping review provided the best solution to understand and specify real context of use for a standardised case finder for detecting lifetime exposure to TBI. Identified case finders were screened for suitability with a focus on any shortcomings which could have implications for practice in a community drug and alcohol treatment service. None of the identified TBI case finding instruments were entirely fit for purpose. Chapter 3 outlines a needs assessment using a scoping review to establish the practice gap between the current position and the intended goal (NHS Innovations South East, 2014). A rationale for the development of a health application for TBI detection is provided.

1.4.2 Specify the patients and staff requirements

Involving stakeholders in the design process was a priority in the development of the health application user interface. A standardised case finder for detecting lifetime exposure to TBI formed the basis of the health application design. Pohl et al. (2007) demonstrated how researchers could enhance the design of a health application through the inclusion of patients and staff in the design process. In this study, user

involvement approaches were adopted to elicit tacit knowledge from patients and staff through fostering collaborative human centred design principles (Weng et al., 2007, Armbrüster et al., 2007). Specific design requirements were considered by involving patients and staff in the development process (Armbrüster et al., 2007). Chapter 4 provides an explanation for the use of expert stakeholder involvement in this study.

A human centred approach to design was not without its limitations. Access to resources, challenges in communication pathways and collaboration between users and designers, combined with a lack of background in usability research influenced outcomes. Chapter 7, provides a comprehensive discussion of the mixed methods findings including the strengths and limitations of conducting usability research in a community drug and alcohol treatment service.

1.4.3 Produce design solutions

Design solutions were developed from patient and staff contextual experiences. The design process was not exclusively dependent upon patient and staff involvement and specialist consultation was required (Rector et al., 1992). Factors which limited the extent of user involvement included comprehension of usability evaluation methods, role responsibilities and how to express ideas (Gould and Lewis, 1985).
Capturing tacit knowledge in healthcare presented a significant challenge when designing a health application for TBI screening (Weng et al., 2007). To mitigate these limitations, usability guidelines were adhered to in the development of the health application user interface (Johnson et al., 2007b). Human centred design and evaluation was an incremental process with rigorous assessment.

Abstract design solutions presented a major challenge for patient experts with suspected neurological deficits who preferred to understand design concepts in a literal, concrete way (Wehmeyer et al., 2004). Paper based prototyping was adopted in an effort to make design ideas more tangible making the design process more inclusive through valuing multiple perspectives (Sefelin et al., 2003). Chapter 5, provides a detailed overview of the design and evaluation procedures used for this study.

1.4.4 Evaluate designs

In this study a prototype user interface developed by patient and staff stakeholder discussion groups underwent formative usability evaluation. Recurrent usability themes in healthcare are mostly centred on navigation, data entry and terminology (Butz and Kruger, 2006). For this study the user interface evaluation extended to technology, page layout and content. To replicate real world test conditions, a formative usability evaluation was conducted in a community drug and alcohol treatment service with patients and staff.

Heathfield et al. (1999) promoted the use of both quantitative and qualitative research methods to increase usability perspective. Most usability testing is formative and the study design is primarily mixed method (Rubin and Chisnell, 2011). In this study the dominant method was qualitative, however, a mix of methods was used to find and fix usability problems through quantifying frequency and severity of identified issues (Rubin and Chisnell, 2011). Chapter 4 discusses challenges to healthcare usability evaluation including methodological issues, testing practicalities and presentation of findings.

In part, achieving good design was about reducing frustration for the end user; an important consideration for patients with TBI (see Chapter 6 where patients share their experiences of living with TBI). Usability evaluation delivered at the appropriate time in the technology development lifecycle offers the best solution for identifying problems in user interface design (Rubin and Chisnell, 2011).

2.0 Background

2.1 What is traumatic brain injury?

In the UK approximately 200,000 people are admitted to hospital annually with head injury (Hodgkinson et al., 2014). For this study the World Health Organisation (WHO) definition of TBI will be used:

> 'If the head is hit by an external mechanical force, the brain will be displaced inside the skull and can be injured against the solid meningeal membrane, the dura, or against the inside of the neurocranium. Acceleration and deceleration forces may disrupt the nervous tissue and blood vessels of the brain'
>
> WHO (2006) pg164

The severity of TBI can vary greatly. 90% of head injuries are classified as mild and have a low mortality rate of less than 1% (WHO, 2006). Fatigue, poor concentration and anxiety are functional neurological impairments associated with mild TBI and are often categorised as post concussional syndrome (ICD-10 F07.2). Severe TBI accounts for 3-5% of head injury hospital admissions and mortality ranges between 20-50% (WHO, 2006). A history of substance use behaviour pre head injury makes the process of diagnosing TBI more challenging (Iverson et al., 2005). It is problematic to reliably differentiate between neurological symptoms of TBI and other causes due to the transient or permanent effects of substance use behaviour (Iverson et al., 2005). Neurobehavioral outcomes for substance using patients potentially have limited reliability in detecting TBI as irritability, agitation, restlessness and aggression are known transient characteristics for patients in early stage drug and alcohol treatment recovery (Baguley et al., 2006). This merits further exploration when the methods of detecting TBI can no longer be relied upon, as substance use behaviour is a prevalent morbidity pre-injury (Corrigan, 1995, Corrigan and Bogner, 2007, Bogner et al., 2001, Kolakowsky-Hayner, 1999, Ruff et al., 1990, Cifu et al., 1996).

2.2 The biomechanics of traumatic brain injury

TBI can be described as either focal or diffuse. A focal injury typically occurs after a fall potentially leading to a fractured skull, cerebral contusions or haemorrhage (Margulies and Hicks, 2009). Diffuse injuries are caused by inertial acceleration of the brain

through whiplash or exposure to a blast (Gennarelli, 1992). The exact mechanics of what causes TBI is not entirely understood, although translational and rotational forces feature. The Centres for Disease Control and Prevention (CDC) (NCIPC, 2016) offers an animated model illustrating the causal mechanisms behind TBI which can be found in figure 2.

Figure 2 - TBI causal mechanisms model

TBI is thought to occur when the soft brain hits the hard, sharp ridges on the inside of the skull damaging the surface of the brain (NCIPC, 2016). The anatomical accuracy of the CDC model (NCIPC, 2016) has been criticised as the animation exaggerates the extent of translational brain movement within the cranial vault following exposure to high velocity forces (Giordano et al., 2014). It is thought cerebral spinal fluid combined with minimal capacity for brain movement serves to limit the extent of widespread axonal injury (Hernandez et al., 2016). In the CDC model the brain moves as one solid mass and this does not represent shearing forces which occur after a rotational impact to the head, leading to axonal straining (Giordano et al., 2014, Gennarelli and Graham, 1998).

Holbourn (1943) made an early predication that the brain does not experience damage solely through translational movement. Animal and computational modelling supported Holbourn's (1943) prediction demonstrating how both coronal and sagittal

rotation are associated with traumatic injury (Browne et al., 2011, Eucker et al., 2011, Smith et al., 2000). Traumatic coma only occurred in non-human primate testing when translational and rotational acceleration were combined (Ommaya and Gennarelli, 1974). Further studies have been conducted which investigated the measurement of human head rotation during impact and found TBI is not something which exclusively occurs to the surface of the brain (Bartsch and Samorezov, 2013, Camarillo et al., 2013, Rowson et al., 2012). Instead damage is thought to originate in the corpus callosum, a fibrous network of nerves connecting the two hemispheres of the brain (Hernandez et al., 2016). Forces from a rotational strike are thought to transmit through the cerebral falx, which descends vertically between the two hemispheres to the corpus callosum (Hernandez et al., 2016). Atrophied corpus callosum and enlarged ventricles are found in patients with chronic traumatic encephalopathy, a neurodegenerative disease associated with multiple head injuries (Broshek et al., 2005).

2.3 Traumatic brain injury classification

Detecting TBI typically involves a series of core questions:

- Have you ever had an injury to your head or neck?
- Did you lose consciousness?
- Were there any changes in cognitive, behavioural, emotional or physiological functioning?

  (Corrigan and Bogner, 2007, Bogner and Corrigan, 2009, Walker et al., 2007, Pitman et al., 2015)

The primary clinical markers for assessing the severity of TBI incorporate the duration of loss of consciousness, post traumatic amnesia, and dazed disorientation and confusion illustrated in table 1.

Table 1 - Traumatic brain injury classification

Severity	Loss of consciousness	Post traumatic amnesia or dazed disorientation and confusion	Glasgow Coma Scale scores
Mild	**Less than 5 minutes**	**Less than 24 hours**	**13-15**
Moderate	**5 – 30 minutes**	**24 hours +**	**9-12**
Severe	**More than 30 minutes**	**24 hours +**	**3-8**

The Glasgow Coma Scale (GCS) is a measure for assessing levels of consciousness with a 15 item scale as part of routine clinical practice in head injury management and early assessment (Jones, 1979).

2.4 Traumatic brain injury prevalence in patients receiving drug and alcohol treatment

Violence is the second leading cause of TBI, behind motor vehicle accidents (Dahmer et al., 1993). Violent TBI is associated with substance use disorder, rather than other TBI aetiology (American Psychiatric Association, 2013, Hanks et al., 2003).
Prevalence for TBI in a substance use treatment group is thought to be in the region of 32-63% for mild-moderate head injury with a median of 53% (Silver et al., 1997). In comparison, there is a prevalence rate for TBI of 8.5% in a general US population (Silver et al., 1997). The available literature has not yet identified the direction of the relationship between TBI and substance use (Walker et al., 2007). Notably, there have been some methodological limitations in how TBI is classified and recorded across studies (Corrigan and Bogner, 2007). This is further compounded as 30% of all head injuries in a substance use population do not receive medical care resulting in no clinical records to obtain leading to an underreporting of head trauma events (Corrigan and Bogner, 2007).

Males between the ages of 15 to 24 are at greater risk of sustaining a TBI (Pitman et al., 2015). In Scotland, rates of head injury are three times higher in males compared to females (Pentland et al., 1986). Females experience more severe injuries and there is a higher fatality rate following head injury (Farace and Alves, 2000). Females who have a partner with substance use behaviour are at higher risk of domestic violence (Kyriacou et al., 1999). Alcohol use pre intentional violence occurred for 51.6% (n=132) of surveyed women (Kyriacou et al., 1999). Domestic violence affects all socioeconomic classes, ethnic groups and ages (Barnett et al., 2005). Typical injuries include being punched, kicked, strangled and assaulted with a weapon (Straus, 1990). Females who have been subjected to domestic violence receiving multiple head injuries are found to have neurological deficits (Corrigan et al., 2003).

Substance use behaviour prior to, during or after a head injury results in greater cognitive impairment (Corrigan and Bogner, 2007). Alcohol frequently becomes a strategy for coping with neurological disability (MacMillan et al., 2002). Increased aggression and violence can be found in patients with impaired executive functioning who use alcohol (Wood and Thomas, 2013, Marsh and Martinovich, 2006). Co-morbid patients consistently have lower Glasgow Coma Scale (GCS) scores at the time of injury compared to patients with TBI who do not use drugs or alcohol (Bigler et al., 1996). GCS scores can remain low for 1-5 years leaving co morbid patients with a persistent disability (De Kruijk et al., 2002, Whitnall et al., 2006, Thornhill et al., 2000). These findings have been further corroborated with neuroimaging studies. High degrees of cerebral atrophy and poor outcome scores following neurological testing, either pre or at the time of injury have been found for substance using patients (Bigler et al., 1996, Ronty et al., 1993, Kasturi and Stein, 2009, Jorge and Starkstein, 2005, Tate, 1999). Atrophic neurological changes from alcohol dependence pre injury could result in more severe pathological impairments with a compromised brain (Bigler et al., 1996). Intoxication increases vulnerability to impact dynamics as defensive reflexes are impaired leading to more severe injury and neurocognitive restrictions (Mearns and Lees-Haley, 1993, Sparadeo et al., 1990).

2.5 Rationale for traumatic brain injury screening in substance use treatment

A lack of awareness of TBI and associated consequences means patients are frequently misdiagnosed (Walker et al., 2007). Patients seeking support from health and social care services will typically present with a co-occurring disorder (HRSA, 2006). By introducing routine TBI screening into health and social care services, resources could be better co-ordinated (Williams, 2012, Graham and Cardon, 2008). There are several TBI case finding instruments available which have been subjected to adaptation to accommodate different health and social care providers' circumstances. Please refer to section 3.4 Collating, summarizing and reporting the findings for an overview of TBI screening instruments which could be adapted to meet the specific needs of a health and social care service provider.

It is feasible patients who use substances and are treatment resistant may in fact have cognitive deficits making treatment engagement problematic. The challenge of

classifying severity of TBI is increased when the patient has recurrent head injuries. Multiple TBI have a cumulative impact on impaired neurological function (Collins et al., 2002). TBI frequently remain undetected in patients receiving drug and alcohol treatment in the UK (Walker et al., 2007). Williams (2012) demanded the introduction of routine TBI screening with at risk patient groups.

2.6 Healthcare technology

This study postulates that the use of health technology could be a potential solution in meeting the clinical knowledge gap through the inclusion of clinical decision support software. The WHO defines health technology as;

> '… the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives'
> (WHO, 2016)

Clinical decision support software is one emerging area of health technology (Bajwa, 2014). Decision support software can be a healthcare application which assists patients and staff in making clinical decisions (Osheroff et al., 2007). The integration of information computer technology in a healthcare setting is not without its challenges. To better understand the role information technology could have in healthcare it is essential to have an awareness of the cognitive work the system would support (Cader et al., 2005). Healthcare technology needs to be sensitive to the requirements and needs of end users adopting the new instruments (Martin et al., 2008). Human centred design offers an approach in how to better ensure clinical decision support systems are usable (Martin et al., 2008).

The objective of healthcare usability research is to support patients and staff in achieving their goals in a specified context of use (ISO, 2010). Usable health technology should strive to meet human centred design standards (ISO, 2010). The relationship between usability and context of use is an important consideration as the extent of usability achieved is context specific (Sicilia and Garcia, 2003). In developing an

instrument which has a high degree of usability consideration was given to patient and staff, tasks, technology and the clinical setting of use (ISO, 2010).

Early instrument development is an iterative process used to discover design options and reveal new directions for design enhancement (Wiklund et al., 2016). Design iteration is more than refinement. In early prototype design each iteration will be subjected to evaluation with the intention of finding and fixing usability problems for redesign (Rubin and Chisnell, 2011). This procedure will shape the technology through a cyclical process of design, test, redesign and retest activities (Agarwal et al., 2010). Human centred design is dependent upon user feedback prior to the next iteration of design (Wiklund et al., 2016). There are multiple methods available to the usability researcher and the procedure is not centred around a single designer (Rubin and Chisnell, 2011). It is typically the case a designer will oversee the instrument development life cycle (Rothwell and Kazanas, 2011). The design process is both systematic and structured shifting from an overarching aim to specific objectives (Wiklund et al., 2016).

Health application technology can be used by both patients and staff. A tool needs to meet the intended users' preferences. Poor design has the potential to result in injury, damage and even fatality (Rubin, 1996). Usability can be wide reaching and transcends age, gender and socioeconomic status (Tullis and Albert, 2013). The complexity of health application technology combined with the diversity of patient users means usability research is having an increasingly important role in health and social care services (Sauro and Lewis, 2016). Usability methods will become a fundamental approach to ensuring complex health application technologies are easy to use and human centred design will become increasingly necessary (Rubin and Chisnell, 2011).

2.7 Traumatic brain injury screening methods

There are a range of assessment methods for detecting severe TBI. These techniques establish whether there have been changes in the brain following injury and determine the risk of emergent problems over time (Corrigan and Bogner, 2007). Computed tomography (CT) scans, magnetic resonance imaging (MRI), diffusion tensor imaging

(DTI) and positron emission tomography (PET) scans are neuro-imaging methods for diagnosing acute or chronic TBI (Corrigan and Bogner, 2007). Current neuro imaging technology lacks the sensitivity for detecting multiple mild to moderate TBI over a lifetime (Belanger et al., 2007).

Collating a history of head injury events and associated symptoms is the primary method for detecting mild TBI as there is seldom physical evidence of brain injury to rely upon (Belanger et al., 2007). Retrospective data collection from clinical records following head injury is vulnerable to under reporting (Corrigan and Bogner, 2007) and historically neuro-imaging is not capable of detecting diffuse axonal injuries, a feature of mild TBI, causing serious problems with cognitive processing (Duhaime et al., 2010). Neuropathological data suggests white matter is more vulnerable to diffuse trauma compared to grey matter (Bigler et al., 1996). Widespread microscopic changes in white matter following mild head trauma has been difficult to detect using traditional neuroimaging techniques (Belanger et al., 2007). Advancements in imaging technology will eventually have the required sensitivity to detect all features associated with brain trauma (Duhaime et al., 2010). However, it is unlikely such technology will be available for routine TBI screening for patients receiving drug and alcohol treatment in the near future. Self-report remains the gold standard for detecting exposure to head injury throughout a lifetime (Olson-Madden et al., 2010). However, self-report cannot confirm the presence of neurobiological damage from head trauma. Furthermore, retrospective self-report is vulnerable to recall bias (Sato and Kawahara, 2011), as there is an expectation for patients to recollect head injuries throughout their lifetime. The process of telescoping means patients forget past injuries (Warner et al., 2005). Deficits in memory are commonly associated with head trauma and related morbidities (Rabinowitz and Levin, 2014). Psychoactive substance use can compromise the patient's capacity to learn, store and retrieve information indicating memory is likely to be impaired in dependent substance using patients (Brown et al., 2000, Solowij and Battisti, 2008, Weinborn et al., 2011).

Deficits in working memory can be found with patients who have mild to severe TBI as features associated with memory are especially vulnerable after head injury

(Rabinowitz and Levin, 2014, Christodoulou et al., 2001). Baddeley and Hitch's (1974) definition of working memory incorporates the short-term storage of information which can be subject to cognitive manipulation. For example, remembering you have a healthcare appointment whilst planning the route to the clinic. TBI can damage regions of the brain which sub-serve working memory (Cohen et al., 1994).

In a study by Gore et al. (2015) memory impairment was found to be an obstacle for patients attempting to engage with psychological therapy for depression whilst receiving community drug and alcohol treatment. Patients found it difficult engaging with psychological therapy as they could not remember appointment dates or recall the reason as to why they wanted to access psychological care (Gore et al., 2015). Cognitive impairment could compromise engagement with recovery treatment plans (Khan et al., 2003). Impaired memory causes difficulties when assimilating new information which could be interpreted as resistance or denial (Walker et al., 2007). TBI screening should occur early in substance use treatment allowing for an appropriate response to neurocognitive deficits with the intention of improving treatment outcomes (Williams, 2012).

2.8 Conclusion

This chapter has provided insight into the biomechanics of head injury (Khan et al., 2003) and a working definition of TBI was offered. The process by which TBI is classified gave an understanding in how self-report screening instruments detect head injury. An overview of methods for detecting TBI was discussed and a rationale formed for the use of retrospective self-report measures. TBI is a prevalent issue for patients receiving drug and alcohol treatment and a case was made for the early detection of head injury for patients in recovery (Walker et al., 2007).

3.0 Needs assessment

3.1 Scoping review purpose

The scoping review was framed to achieve a broad and clearly specified search of the available evidence. Arksey and O'Malley (2005) methodological framework for conducting a scoping review was adhered to. The scoping review had four stages:

- Identifying the research question
- Identifying relevant studies
- Study selection
- Collating, summarising and reporting the results

(Arksey and O'Malley, 2005)

To ensure an answerable question was formulated consideration was given to required elements for the scoping review. The purpose of the review was to identify available case finder instruments for detecting lifetime exposure to TBI in patients receiving drug and alcohol treatment, and establish whether there were any implications for practice. Diagnostic validation studies were prioritised in the identification of relevant articles.

The report 'Repairing Shattered Lives' (Williams, 2012) offered recommendations for TBI screening. The TBI screening guidance formed the basis for six design criteria for appraising identified measures in the scoping review:

- instrument must be brief
- non-invasive
- self-completing and mitigate the need for a trained professional
- accessible to a range of different service providers
- portable and can be used in the community
- not dependent on reading ability

3.2 Developing the search strategy

In an effort to conduct a comprehensive search of the available literature the following bibliographic databases were used; PsycINFO (1806 – 7/12/2012), Embase (1947 – 7/12/2012), Web of Knowledge (1900 – 7/12/2012) and Medline (1946 – 7/12/2012). Some of the key search terms included; reliability, predictive validity, case finder,

traumatic brain injury and substance use. The initial search was limited to humans and English and was completed in December 2012. An updated search was completed in November 2016, one further relevant study was identified (Pitman et al., 2015). It is acknowledged that some potentially relevant articles could have been overlooked through restricting the search to English language publications. Seven lists of relevant key words were generated, using 'AND' and 'OR' Boolean operators (Gerrish and Lacey, 2010) to link free text terms and subject headings. A full description of the search strategy can be found in appendix B.

3.3 Selecting the studies

After the initial search was completed a sifting table was used to help select the most relevant TBI case finding instruments which have undergone diagnostic validation (see appendix C for sifting table). The rationale for study selection was based upon the need to identify TBI case finding instruments which had been validated with patients receiving drug and alcohol treatment.

Studies were selected if they met the following inclusion criteria:

- Instrument validation studies for TBI case finders
- Implications for practice were offered
- Drug and/or alcohol treatment setting
- Were published in a peer-reviewed journal
- Were unpublished articles
- Were published in English

Exclusion criteria:

- Not an instrument validation study for TBI case finders
- No implications for practice were offered
- Not drug and/or alcohol treatment setting
- Were not published in English

The selection process for identifying relevant articles was iterative (Levac et al., 2010). Two studies were initially identified and a further article discovered in November 2016 (Corrigan and Bogner, 2007, Bogner and Corrigan, 2009, Pitman et al., 2015). A title and abstract review was completed to apply the inclusion and exclusion criteria listed

above, only one article remained for full-text review (Corrigan and Bogner, 2007). 41 articles were hand reviewed from the reference lists of the identified article (Corrigan and Bogner, 2007)(See appendix D). Articles were excluded by title and abstract review. One online publication providing a repository of TBI screening instruments was retained (HRSA, 2006). In total 21 TBI case finder instruments were identified and can be found in appendix E.

Six out of the 21 TBI case finders were designated for use with patients receiving drug and alcohol treatment. Three of the instruments detected lifetime exposure to TBI:

- Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID)
- Iowa Head Injury Screening Instrument (IHISI)
- Screening Tool for Dual Diagnosis and TBI (STDDT)

The remaining three instruments were not available for review due to broken hyperlinks in the TBI repository (HRSA, 2006):

- Brief TBI Screening (BTS)
- TBI Screening Tip Sheet (TSTS)
- Brain Injury Screening Form (BISF)

Bibliographic databases were used to search for the three inaccessible TBI case finding instruments, no positive search results were found. The TBI repository was revisited and the Brain Injury Screening Questionnaire (BISQ)(MSICRC, 1998) was identified as being designated for use with multiple patient groups for detecting lifetime exposure to TBI (HRSA, 2006). A final search was conducted using bibliographic databases to identify potentially relevant diagnostic validation studies with the BISQ, the IHISI and the STDD. A sifting table was used to help select the most relevant studies (see appendix F for sifting table). 25 articles were reviewed by title and abstract applying the inclusion and exclusion criteria listed above, one article remained for full-text review (Sacks et al., 2009).

Only one instrument underwent diagnostic validation and reliability testing with patients receiving drug and alcohol treatment, the OSU TBI-ID (Corrigan and Bogner, 2007). However, the scoping review revealed the BISQ had been used to detect TBI in

patients receiving drug and alcohol treatment in an observational analytic study and could have face validity (Sacks et al., 2009, Nevo, 1985). Given the paucity of available evidence for TBI case finding instruments which have been diagnostically validated with patients receiving drug and alcohol treatment only two instruments remained for design appraisal, the BISQ (Sacks et al., 2009, MSICRC, 1998) and the OSU TBI-ID (Corrigan and Bogner, 2007). The rationale for not including other TBI case finders which had undergone diagnostic validation with at risk TBI populations was the need for measures which could differentiate between symptoms associated with TBI versus substance intoxication at time of head injury (Iverson et al., 2005, Corrigan and Bogner, 2007).

3.4 Collating, summarizing and reporting the findings

The OSU TBI-ID and BISQ were considered relevant for further investigation. This section matched the two measures against the six design criteria illustrated in section 3.1 Scoping review purpose.

The OSU TBI-ID and the BISQ were based on different conceptual definitions of TBI which could have implications for screening outcomes by either the over or underreporting of TBI occurrence. The OSU TBI-ID was based on Centre for Disease Control and Prevention's (CDC) criteria for assessing lifetime exposure to TBI (CDC, 2008). The BISQ was based on the American Congress of Rehabilitation Medicine (ACRM) definition of TBI (ACRM, 1993). The sensitivity of the measures for detecting TBI was beyond the purpose of this scoping review.

3.4.1 Brief

The OSU TBI-ID did not specify length of time to complete, however, it did come in two versions, long and short (Corrigan and Bogner, 2007). The BISQ had three sections (Sacks et al., 2009). The instrument took between 5-30 minutes to complete. Part 1 took approximately 5 minutes to administer if clinical markers associated with TBI were not detected (Sacks et al., 2009). If TBI markers were detected parts 2 and 3 were completed (Sacks et al., 2009).

3.4.2 Non-invasive

Both measures were non-invasive (Corrigan and Bogner, 2007, Sacks et al., 2009). The OSU TBI-ID was administered via semi-structured interview (Corrigan and Bogner, 2007) and the BISQ was a questionnaire (Sacks et al., 2009).

3.4.3 Self-completing and mitigate the need for a trained professional

Neither instrument was self-completed by patients receiving drug and alcohol treatment (Corrigan and Bogner, 2007, Sacks et al., 2009).

The OSU TBI-ID required a trained interviewer, with a background in brain injuries rehabilitation, to be administered (Corrigan and Bogner, 2007, Bogner and Corrigan, 2009). For patients with co-morbidity TBI detection was more complex (Iverson et al., 2005). The OSU TBI-ID had been validated with patients receiving drug and alcohol treatment. The interviewer required specific training in how to distinguish between altered states of consciousness due to substance intoxication versus TBI symptoms (Bogner and Corrigan, 2009, Corrigan and Bogner, 2007). This was achieved by the interviewer prioritising TBI events which resulted in the loss of consciousness rather than altered states of consciousness (Corrigan and Bogner, 2007).

The BISQ can be self-completed or by proxy, however, the measure was administered by a trained interviewer when completed with patients receiving drug and alcohol treatment (Sacks et al., 2009). Part 3 of the BISQ attempted to differentiate co-occurring factors e.g. mental health disorders, substance use and medications from TBI impairment (Sacks et al., 2009). The training demands of both instruments could be a limiting factor for wider adoption in drug and alcohol treatment services.

3.4.4 Accessible to a range of different service providers

The OSU TBI-ID had been validated with substance users and offenders (Corrigan and Bogner, 2007, Bogner and Corrigan, 2009). However, there was limited available evidence to comment on the accessibility across health and social care settings with different treatment populations (Corrigan and Bogner, 2007, Bogner and Corrigan, 2009).

The BISQ had been widely used in observational analytic studies across seven high risk TBI populations; homeless people, persons with HIV seeking vocational rehabilitation, youth offenders, public school children, substance users, intercollegiate athletes and other community based samples (Brown et al., 2014).
Both measures required further empirical validation and reliability testing with wider TBI treatment populations.

3.4.5 Portable and can be used in the community

Both measures were paper based and could be considered portable (Corrigan and Bogner, 2007, Sacks et al., 2009). The BISQ was available online for data collection and survey results were not presented after completion of the measure (MSICRC, 1998).

3.4.6 Not dependent on reading ability

The OSU TBI-ID was administered by an interviewer, making the instrument not dependent on patient reading ability (Corrigan and Bogner, 2007, Bogner and Corrigan, 2009). The BISQ had 113 questions (HRSA, 2006) and was dependent upon reading ability if the measure was not completed with a trained interviewer. An instrument which could be self-completed by patients with low reading ability could have a beneficial impact in the wider adoption of TBI screening in drug and alcohol treatment making the screening process more collaborative and inclusive.

3.5 TBI screening implications for practice in community drug and alcohol treatment

The OSU TBI-ID (Corrigan and Bogner, 2007) and the BISQ (MSICRC, 1998) differed in two ways; method of enquiry and administration time. Neither method was entirely fit for purpose as an initial case finder for TBI in a drug and alcohol treatment service. The length of the BISQ was a major concern with 113 questions to complete, taking up to 30 minutes to administer (Sacks et al., 2009, HRSA, 2006). The measure was not brief and could discourage under pressure staff from conducting TBI screening in a busy drug and alcohol treatment service. The cost of training required to ensure all health and social care professionals had sufficient skill in conducting the OSU TBI-ID could be prohibitive. Logistically, the co-ordination of inter-professional training as part of a common health assessment framework for TBI screening would be a complex

undertaking. A potentially more cost effective solution would be to convert clinical tacit knowledge into a computerised rule based decision algorithm. In recent years, there has been an emerging interest in clinical decision support software in healthcare (Free et al., 2013). Examples of these can be found in NHS triage services (O'Cathain et al., 2004, Fitzmaurice et al., 2002, Vadher et al., 1997). Decision support software would guide the health and social care professional in how to conduct TBI screening with their at risk populations, mitigating the need for a clinical background in brain injury rehabilitation. A health application offers portability with the increased use of smart phone and tablet computer technology in healthcare (Free et al., 2013).

The OSU TBI-ID had greater relevance for this study as it was specifically validated with patients receiving drug and alcohol treatment and a brief version had been developed (Corrigan and Bogner, 2007, Bogner and Corrigan, 2009). This measure could form the basis of an adapted computerised TBI case finder. Permission was granted by Corrigan and Bogner for the OSU TBI-ID to be administered via a mobile enabled web-based application (see appendix G for research version).

3.6 Competitive analysis

There are several application stores which supply health applications for clinical staff. Many of the available applications have not undergone empirical validation or clinical certification from a professional body (NHS Innovations South East, 2014). Before committing resources to the adaptation of a case finding instrument for detecting lifetime exposure to TBI a search was conducted to determine whether an appropriate health application was available. Competitor applications were identified across platforms through searching Playstore, AppStore, and Windows Apps. Key search terms included; ‘traumatic brain injury’, ‘head injury’ and ’concussion’. In total 47 health and medical applications associated with TBI were identified across platforms (see appendix H for reviewed health applications). None of the identified applications were screening instruments for lifetime exposure to TBI. 17 health applications were concussion assessment tools for veterans and sports related injuries, the 30 remaining applications provided educational resources for head injury assessment, management, and rehabilitation. The head injury assessment tools identified were for individual head trauma events and not lifetime exposure to TBI. None of the instruments were CE

marked suggesting they had not undergone European conformity assessment for medical devices (MHRA, 2016).

3.7 Conclusion

A scoping review identified two relevant case finders for detecting lifetime exposure to TBI (Corrigan and Bogner, 2007, Sacks et al., 2009). Two limitations were noted with the instruments; administration times and training requirements. Health application technology with embedded clinical decision support software was suggested as a potential solution in how the OSU TBI-ID could be administered, mitigating the need for a trained professional. A competitive analysis revealed there were no available health applications for detecting lifetime exposure to TBI. This study proposes the adaptation of the OSU TBI-ID into a mobile health application.

4.0 Methodology

4.1 Introduction

This chapter outlines the methodological underpinnings adopted for this study when undertaking human centred design and evaluation. Methodological approaches to human centred design and evaluation research are discussed and a rationale for the chosen theoretical orientation provided. Formative usability testing is rooted in a mixed methods paradigm drawing upon both qualitative and quantitative usability perspectives when capturing patient and staff experiences in design and evaluation. An exploration of concurrent mixed method approaches to health application development is provided. The strengths and weaknesses of specific design and evaluation techniques in early user interface development are discussed. Formative sampling models were discussed and recommendations given in relation to sampling strategies when detecting usability problems. Qualitative and quantitative methods of analysing formative usability data are given. The three ethical principles of autonomy, beneficence and justice are discussed in the context of mixed methods usability research with patients who have complex needs. The chapter concludes with a reflexive account of conducting the study which embodies human centred principles of design and evaluation holding the end user at the centre of instrument development.

4.2 Research methodologies

The effective design and evaluation of health application technology is currently receiving much interest. Health application technology needs to demonstrate it is usable, meets patient and staff needs and most importantly is safe (Kamel Boulos et al., 2014). The virtues of specific methodological approaches for conducting usability studies have received little attention (Peute et al., 2008).

4.2.1 Quantitative

Positivism resonates with the hypothetico–deductive method (Cacioppo et al., 2004, Sciarra, 1999). This experimental approach involves systematic observation and description of phenomena contextualized within a model or theory using inferential statistics to test hypotheses (Cacioppo et al., 2004). Positivists believe there is a true and identifiable reality which can be described in terms of categories and large

samples will reveal the laws of nature (Mill, 1843). Summative usability research tends to quantify the user's experience (Tullis and Albert, 2013). Prototype designs can be compared and evaluated in terms of their efficiency, effectiveness and satisfaction in use (Tullis and Albert, 2010).

4.2.2 Qualitative

The constructivist or interpretivist paradigm (Ponterotto, 2005) assumes there are multiple equally valid realities (Schwandt, 1994) constructed by the mind of the individual (Hansen, 2004). This relativist position uses the process of deep reflection as a method of investigation (Schwandt, 2000, Sciarra, 1999). The interaction between researcher and participant is the distinguishing mechanism from which deeper understanding can be achieved (Ponterotto, 2005). The ontological distinguishing feature for constructivism is that it is not feasible to separate out an objective reality from the participants lived experience of a historic social reality (Mertens, 2014). Qualitative enquiry is usually the dominant method found in formative usability research and could reveal solutions to redesign through rich problem description (Morgan, 1998).

4.2.3 Mixed methods

A schism has emerged over the past hundred years amongst paradigm hardliners who have entrenched themselves in either positivist or constructivist philosophies (Campbell and Stanley, 2015, Guba and Lincoln, 1982) this has been dubbed the paradigm wars (Howe, 1988). Promoters of the incompatibility thesis hold the position qualitative and quantitative research methods cannot and should not be mixed (Howe, 1988, Johnson and Onwuegbuzie, 2004).

Mixed methods research has been described as the third paradigm and has the potential to bridge the commonalities between the philosophies (Johnson and Onwuegbuzie, 2004). Use of objectives and process of enquiry is consistent throughout methods and paradigms (Dzurec and Abraham, 1993). Knowing which method to use and when it is appropriate to mix requires a researcher who is informed in epistemological and methodological pluralism, perhaps leading to more effective

research (Johnson and Onwuegbuzie, 2004). Formative usability research embraces the mixed methods paradigm, valuing multiple perspectives for problem identification and idea generation (Molich et al., 2004).

4.3 Theoretical orientation

Balancing the methodological tensions of mixed methods research is necessary when selecting a research design (Tashakkori and Teddlie, 2010). Pragmatism offers a way forwards for researchers who want to purposefully mix both qualitative and quantitative data sets and discard the dichotomy of post positivism and constructivism (Johnson and Onwuegbuzie, 2004). Pragmatism finds its roots with three American Philosophical thinkers; Charles Sanders Pierce, William James and John Dewey. There is no one definition for what is meant by pragmatism (Peirce, 1905). Professional backgrounds and topics of enquiry influences the many different interpretations of the pragmatic approach (Morgan, 2007).

Pragmatism has a strong association with mixed methods research design as the priority is orientated towards the question under investigation and not the multiple methods of data collection available (Creswell, 2013). This does not mean a pragmatic philosophy should be wholly adopted without full consideration of the paradigm's characteristics and how they best complement a mixed methods approach (Tashakkori and Teddlie, 2010). A pragmatic methodology values abductive reasoning through a process of converting observations into theory and implementing those theories into practice (Morgan, 2007). In mixed methods literature pragmatism has been characterised in a philosophical framework by Johnson and Onwuegbuzie (2004) and provides a basis for the researcher to design and conduct mixed methods research.

Bryman (1984)and Niglas (2004) both demonstrated that clinical practitioners are primarily directed by technical rationale as opposed to epistemology when selecting methods, suggesting that methodology is in fact commonly, 'agnostic to epistemology' (Scott and Briggs, 2009, pg231). Clinical decision making is ultimately pragmatic (Scott and Briggs, 2009). The health application developed in this formative usability study is an example of a clinical tool. The instrument makes clinical decisions based on a

plurality of data and interpretations. Clinical reasoning is inherently abductive and mixes qualitative patient and staff experience with quantitative test results (Scott and Briggs, 2009).

There are many definitions of mixed methods including research processes, philosophy, and research design (Creswell and Plano-Clark, 2011). Johnson et al. (2007a) set themselves the challenge of defining the term mixed methods research. They reviewed 19 definitions by 21 leading researchers (Creswell and Plano-Clark, 2011). Johnson et al. (2007a, pg123) synthesised their different ideas and produced a composite definition:

> 'Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the purposes of breadth and depth of understanding and corroboration'.
>
> (Johnson et al., 2007a)

There are many mixed methods typologies available to the usability researcher and consideration needs to be given to the paradigm emphasis (Morgan, 1998). The mixed methods design can either be predominantly qualitative or quantitative or both paradigms can have equal status (Morgan, 1998). A further dimension to the formation of the research design is time ordering, selecting whether the method should be mixed sequentially or concurrently (Johnson and Onwuegbuzie, 2004).

To offer a more precise examination of mixed methods design review, Venkatesh et al. (2013) provides useful guidance. For usability research where the objective is to develop software then a concurrent mixed methods research design should be used (Venkatesh et al., 2013). The concurrent approach enables the usability evaluator to test redesigned iterations over time (Bhattacherjee and Premkumar, 2004).

4.3.1 Concurrent design

Creswell (2009) proposed three different categories of concurrent research designs; triangulation, embedded and transformative. Concurrent mixed methods research designs collect qualitative and quantitative data simultaneously (Andrew and нalcomb, 2009). Methods can be differentiated by the priority given to each data type, the stage data is integrated and whether the research is guided by a specific theoretical perspective (Terrell, 2012).

4.3.2 Concurrent triangulation

Triangulation is a concurrent mixed methods design (Creswell, 2009). The classic intent is to evaluate whether there is convergence or differences amongst the qualitative and quantitative data sets (Greene et al., 1989). Weighting of data types is typically equal for this design strategy, however, in practice there can be a dominant method (Creswell and Plano-Clark, 2011). A high degree of expertise is required using two different methods to examine a specific phenomenon (Creswell, 2009). The issue of how best to resolve discrepancies requires consideration. There are available procedures and these might involve further data collection through formulating a research project which addresses the discrepancy, supporting the iterative approach of usability research (Creswell, 2009).

4.3.3 Concurrent embedded

The embedded design has a dominant data type which guides a secondary nested method, a key requirement for this study. The qualitative method is typically dominant to gain an understanding of the nature of problems with the design (Creswell, 2013). Rich problem descriptions from a qualitative method (see section 5.6.7 Qualitative – cognitive walkthrough) can be used to inform a quantitative method (see section 5.6.8 Quantitative – problem discovery) to help prioritise areas for redesign. Exclusive dependence on quantitative methods of enquiry would not suffice for idea generation when solving identified usability problems (Creswell, 2013). The different methods can address different research questions which was not necessary for this study (Gollob and Reichardt, 1987). The mixing of data typically occurs within the discussion section offering less flexibility in how the research findings can be presented (Creswell and

Plano-Clark, 2011). Despite this limitation, the different data types can be presented separately and not compared. With the embedded approach integration of data can present a challenge especially when the methods are addressing different research questions (Creswell and Plano-Clark, 2011). The dominant method can be informed by a theoretical perspective (Creswell, 2009). The primary benefit of this design is that it has the capacity to offer a broader overview of a research topic through having the advantage of both qualitative and quantitative research methods (Morse, 1991).

4.3.4 Concurrent transformative

A transformative design is guided by a theoretical perspective and can adopt the features of either an embedded or triangulated strategy (Creswell, 2009). The theoretical perspective of the study is the driver behind the choice of methodology, problem definition, study design, data analysis and interpretation of findings (Creswell, 2009). Data can be mixed through merging, connecting or embedding (Creswell and Plano-Clark, 2011). The transformative approach has the same strengths and limitations as the other concurrent designs as they share many of the same features (Creswell, 2009).

4.4 Phase one: Understanding and specifying context of use with literature review and synthesis

There are multiple review types with associated methodologies and this section will offer a broad overview of their strengths and weaknesses in relation to the topic under investigation. There are many commonalities amongst the most frequently used typologies and for this reason the discussion will be limited to four review types (Grant and Booth, 2009).

4.4.1 Systematic review

Systematic review is the most well-known type of review method and there are specific guidelines available for the appraisal and synthesis of evidence (Higgins et al., 2002). This review type attempts to undertake a comprehensive search for all available evidence on a specific research topic (Grant and Booth, 2009). It is crucial the systematic method is transparent and reproducible (Gerrish and Lacey, 2010). In the

early years of the Cochrane Collaboration the search strategy was restricted to one study type, typically randomised controlled trials (RCT) (Godlee, 1994, Grant and Booth, 2009) making it feasible to evaluate effectiveness (Gerrish and Lacey, 2010). Meta-analysis can be used to consolidate statistical findings from multiple homogenous quantitative studies. By assimilating findings from smaller studies a more precise effect of the results can be offered (Grant and Booth, 2009). A lack of available literature on a specific topic reduces the feasibility of applying a systematic review methodology (Grant and Booth, 2009). This review type had limited utility for the topic under investigation for this study as the question focus is on instrument development and not intervention effectiveness (Gerrish and Lacey, 2010).

4.4.2 Qualitative review

A qualitative systematic review is a method for interpreting and comparing qualitative literature (Grant and Booth, 2009). Meta-synthesis or meta-ethnography are terms used to describe qualitative systematic review. The process is interpretivist in gaining a more comprehensive understanding of a specific phenomenon (Gerrish and Lacey, 2010). The synthesis of the evidence identifies themes or constructs across studies (Booth, 2001).

There is emerging consensus in guidelines on how to conduct qualitative systematic reviews (Grant and Booth, 2009). Despite the establishment of qualitative review operating principles, there remains much debate as to when to apply this specific method (Booth, 2001). A decision needs to be made as to whether the priority is to identify as many qualitative studies as possible or to use an appropriate sampling method to select papers which build a holistic interpretation of a phenomenon (Greenhalgh, 2001). In early stage instrument development neither approach would entirely capture the topic under investigation as the available literature crosses paradigms bringing together quantitative diagnostic validation studies with qualitative observational studies (Molich et al., 2004).

4.4.3 Mixed methods review

A mixed methods review can incorporate a range of methods in which one method is a literature review and is typically systematic (Grant and Booth, 2009). The mixed methods review type is mostly used to answer the more complex question of 'what works under which circumstances' (Grant and Booth, 2009, pg26) by bringing together what is effective with how it works (Booth, 2001).

This type of review offers a comprehensive perspective of the research terrain. Review team burden is a major consideration due to the challenges of increased time demand. The difficulties of mixed method integration of both aggregative and interpretative methods of synthesis can make this review type less favourable (Mulrow, 1994).

In this study the extent, range and nature of research activity was not known making it difficult to justify the use of review type which incorporates a systematic literature review (Levac et al., 2010).

4.4.4 Scoping review

This type of review provides a preliminary assessment of the potential size and scope of available research literature (Grant and Booth, 2009). It aims to identify the nature and extent of research evidence, usually including ongoing research. They can provide the basis for the justification of a full systematic review or identify gaps in the literature (Levac et al., 2010). A high quality scoping review should be both systematic and reproducible (Andrew and нalcomb, 2009). Scoping review rigour is frequently criticised as they are more vulnerable to the issue of bias (Levac et al., 2010). There are contradictory positions on whether scoping review findings can be used to advance policy and practice. Grant and Booth (2009) argue the identified literature is not subject to quality assessment and any recommendations from findings cannot be used to develop policy and practice. However, Levac et al. (2010) suggest scoping review findings can have broad implications for practice, research and policy.

Williams (2012) report identified a need for routine TBI screening in patients receiving community drug and alcohol treatment. This study was a response to the identified

treatment gap. A scoping review offers a method for mapping the available literature in this area of interest (Arksey and O'Malley, 2005). The purpose of the review was to identify available case finding instruments for detecting lifetime exposure to TBI in patients receiving drug and alcohol treatment and establish whether there were any implications for practice.

4.5 Phase two: Specifying patient and staff requirements through stakeholder involvement

There is a strong culture within healthcare research for the use of patient and public involvement (PPI). The National Institute for Healthcare Research (NIHR) has been funding PPI for the past 20 years in the UK. The national advisory group for PPI has been developing an evidence base to evaluate the impact of patient and public participation in health and social care research. It is generally accepted that public involvement should occur at every stage throughout the research process (ınvolve, 2014). This leads to the development of instruments which are more relevant, accessible and have higher acceptability amongst participants. Stakeholder consultation is a prevalent research method employed in formative usability design and evaluation studies for early instrument development (Curry et al., 1999, Elwyn et al., 2011, Witteman et al., 2015). Partnership working in usability research with various stakeholders can dispel potential misgivings and foster a milieu of trust and understanding (Cowan, 2010).

Stakeholder involvement has been subject to much criticism from an implementation perspective as there was little guidance on how, when and to what extent to involve patients and staff in the research process (Cowan, 2010). Despite these weaknesses the personal knowledge patients with TBI could offer meant that useful insight about this issue under investigation could be gained (ınvolve, 2014).

Stakeholder expertise is useful when there is minimal knowledge or uncertainty about the area of interest (Hardy et al., 2007). Early instrument development commences from a point of uncertainty and exclusive dependence on technical experts is unadvisable (Stoddart et al., 2006). This could justify the use of stakeholder opinion

enhancing design credibility through the involvement of patients and staff as content experts (Stoddart et al., 2006). Contentiously there are no set guidelines in literature as to how to define what is meant by expert, making the selection and identification of expert members problematic (Parenté et al., 1984, Baker et al., 2006).

A small homogenous sample could lead to the identification of stakeholders who meet the condition of representativeness. Inclusion criteria for patient and staff expertise requires consideration (Stoddart et al., 2006). For this study expertise could be defined as lived or practice based experience of TBI in a community drug and alcohol treatment service. There is no available evidence to support the use of a predetermined level of experience when recruiting expert patients and staff (Hardy et al., 2007).

Staff work based knowledge and patients who have exposure to TBI will offer valuable lived experience. Stakeholder expertise can offer insight into the instrument's development, however, there is no evidence to support the use of patient or staff involvement from a technical perspective suggesting a degree of specialist consultation may be required (Baker et al., 2006).

Knowledge is one characteristic which could define a technical expert (Williams and Webb, 1994). Technical knowledge does not necessarily equate to expertise but possession of a relevant qualification could infer credibility (Hardy et al., 2007). Another practice of determining knowledge expertise is through the selection of technical experts through their published work (Jones and Hunter, 1995). At the opposite end of the spectrum studies have simply relied upon the subjective opinion of the researcher as to who they believe constitutes an expert (McBride et al., 2012). The latter option may be the only pragmatic solution to the identification of technical experts as access to appropriate and willing expertise could be in short supply. In this eventuality safeguards should be taken to ensure the technical expert is not know personally to the research team (Skolarus et al., 2011).

In early instrument design a wider range of ideas is valued over the commonality of design suggestions. This approach mitigates the risk of marginalising patients who may not use the same language as members of staff (Baker et al., 2006). Stakeholder perspectives as instrument developers can ratify a prototype user interface design for ease of use prior to usability testing (Elwyn et al., 2011).

4.6 Phase three: Produce design solutions with usability research methods

Usability evaluation research tends to fall into two broad methods of enquiry which have been defined as formative and summative assessment methods (Scriven, 1967). To offer a more concise discussion this section will exclusively focus on formative testing, or in other words a range of methods to find and fix usability problems (Sauro and Lewis, 2016). Formative evaluation offers a mechanism to include a specified patient group in the design and development process (Boy and Riedel, 2009). With the ever growing sophistication of software applications there is a call to provide designers with new evaluation methods for formative assessment (Kushniruk et al., 2011).

Typically, formative usability studies do not rely upon one single method (Borgholm and Madsen, 1999, Gulliksen et al., 2004, Ebling and John, 2000, Peleg et al., 2009, Scott, 2008, Zabed Ahmed, 2008). Instead Molich et al. (2004) concluded that an appropriate mix of methods was required after reviewing how different organisations conducted formative evaluations.

4.6.1 Qualitative usability methods

Eye tracker, paper prototypes, remote testing and cognitive walkthrough are all usability evaluation methods (UEM) used to reveal potential usability problems with initial prototype designs (Dumas and Redish, 1999). Each evaluation method has its own distinct qualities in uncovering usability issues.

In recent years eye tracking technology has become much more accessible due to increased affordability (Duchowski, 2002). Determining what data set is most important (e.g. eye fixation, duration and pupil diameter) and what this indicates about the application is one of the greatest challenges with eye-tracking technology

(Le Meur and Baccino, 2013). To assist with this, decision usability evaluation methods can be combined to gain a richer understanding of the user experience (Sibert et al., 2000).

Paper prototyping offers a low tech solution for usability evaluation (Snyder, 2003). This evaluation technique is good at detecting issues with terminology, navigation, content and page layout and is very cost effective (Snyder, 2003). The main disadvantage of paper based prototypes is that they do not truly replicate digital models of health applications as it is not feasible to demonstrate features such as scrolling, data entry, download time and the overall appearance of the visual interface (Sauer et al., 2010).

Once the design cycle has progressed to the development of a prototype health application, the mixed methods approach to remote usability testing is frequently employed (Huang, 2005). This method has several benefits over traditional task based performance testing which typically requires the provision of a test laboratory, test administrator plus audio and visual recording equipment (Thompson et al., 2004). Remote usability testing reduces some of the costs associated with the traditional task based method through giving the end user the option of completing the test either at home or work if they have an internet connection (Thompson et al., 2004). This real life implementation can also create a more realistic test environment (Dray and Siegel, 2004). The main weakness associated with remote usability testing is that users who do not have access to very specific equipment and skills e.g. PC, internet, telephone headset and reasonable IT capability may not be able to take part in the test process (Thompson et al., 2004). Patients in community drug and alcohol treatment services tend to come from socioeconomic disadvantaged backgrounds and potentially do not have access to the type of technology required for remote usability testing (Galea et al., 2004).

The cognitive walkthrough method (Polson et al., 1992, Wharton and Lewis, 1994) evaluates design through exploration, focusing primarily on the user's cognitive processes when completing a specific task (Wharton and Lewis, 1994). Design

problems are revealed to the practitioner when the user interacts with the task, by discovering barriers to “learning by exploration” (Andre et al, 2003, p.462) and problems with on-screen content (Wharton and Lewis, 1994). This task orientated approach to evaluation, makes it possible to determine how well the design structure works together (Andre et al., 2003). Cognitive walkthrough has enhanced sensitivity, in comparison to other usability evaluation methods, when identifying generic usability issues (Van Velsen et al., 2013).

A criticism of the cognitive walkthrough technique is that it does not reflect how a person would normally interact with a software application, seemingly at odds with the drive to make the test environment as realistic as possible (Kushniruk et al., 2011). To further this point, Pirolli et al. (2005) appraised several studies where the cognitive walkthrough technique improved performance, potentially resulting in an underestimation of usability problems. The technique demands a background knowledge in cognitive theory of exploration and has been described as both tedious and time consuming (Polson et al., 1992, Blackmon et al., 2002, Wharton and Lewis, 1994, Desurvire et al., 1992). This opinion does not consider:

- the nature of tasks set for testing
- evaluator interpretations
- individual differences amongst participants

  (Hornbæk, 2010, p.108)

Despite these limitations, in usability literature the cognitive walkthrough technique is regarded as the gold standard to which all other usability evaluation methods should be held (Van Velsen et al., 2013, Hornbæk, 2010).

This is by no means an exhaustive list of usability design and evaluation methods available to the usability researcher. There are many factors which could influence the decision process the usability evaluator may go through when selecting from their toolkit and these can be driven by cost, training and accessibility to equipment and expertise combined with what specific usability issues are a priority in the design cycle (Beyer and Holtzblatt, 1997).

4.6.2 Quantitative usability methods

Problem discovery is a useful usability evaluation method for prototype designs which have not previously undergone usability testing. The method is especially helpful if you do not have any preconceived ideas about what participants may find problematic (Tullis and Albert, 2013). Problem discovery enables the evaluator to create test conditions which have a high degree of realism. However, usability performance cannot be compared between participants as predefined usability tasks are not set (Turner et al., 2006).

Issue based metrics can be used to catalogue the frequency and severity of identified usability problems in predefined areas using the problem discovery method(Tullis and Albert, 2013). With this technique usability data is recorded in terms of a problem type, frequency and severity (Creswell, 2009). Usability problems can be generalised into predefined categories, for example, navigation, page layout and terminology (Hertzum and Clemmensen, 2012). By examining specific issues in terms of their frequency and severity a redesign priority shortlist can be achieved (Tullis and Albert, 2013).

There are many factors which influence the detection of usability problems including number and expertise of evaluators, test environment, and the competency of participants (Lewis, 2001). More severe problems have a higher detection rate than less severe usability problems (Nielsen, 1992, Virzi, 1992). As there are no objectively defined criteria for identifying usability problems, problem discovery can lead to potential discrepancy between evaluators (Hertzum and Clemmensen, 2012).

4.7 Sampling

There is no clear consensus over the number of participants required to detect usability problems and sampling models for formative usability testing have come under much criticism (Spool and Schroeder, 2001, Woolrych et al., 2011). The effect of participant and task heterogeneity across formative usability studies is frequently underestimated and sampling models offer limited utility (Hornbæk, 2010). However, Lewis (2006) considered four participants per group to have a highly accurate detection rate in formative usability research. The small sample size is based on

rigorous analytical evaluations of formative usability study data illustrating a small sample size can detect most usability problems (Wiklund et al., 2016).

Table 2 provides sample size requirements for formative usability research (Sauro and Lewis, 2016).

Table 2 - Likelihood of discovery for various sample sizes

P	n=1	n=2	n=3	n=4	n=5
0.01	0.01	0.02	0.03	0.04	0.05
0.05	0.05	0.10	0.14	0.19	0.23
0.10	0.10	0.19	0.27	0.34	0.41
0.15	0.15	0.28	0.39	0.48	0.56
0.25	0.25	0.44	0.58	0.68	0.76
0.50	0.50	0.75	0.88	0.94	0.97
0.90	0.90	0.99	1.00	1.00	1.00

(Sauro and Lewis, 2016, p147)

Formative usability research studies do not typically seek representativeness through random sampling, although recruiting participants who meet the target population criteria enhances credibility (Lewis, 2006). The sampling process should gain a good cross section of participants who represent the individuals using the health application (Wiklund et al., 2016). Purposive sampling could be used to ensure relatively equal distributions of participants according to variables that distinguish between datasets, including whether they were a patient or staff member and by gender. This would enable the evaluation of potential interactions between different groups (Lewis, 2006).

Recruiting a sample group with above average limitations could impact upon participants' ability to use the software application leading to a higher detection rate of usability problems (Tullis and Albert, 2013). Usability evaluators can intentionally skew the sample to detect severe usability problems by recruiting participants with more severe impairments (Wiklund et al., 2011). Specifically recruiting patients with suspected TBI could reveal the cognitive accessibility of a prototype health application. Purposive non-probability sampling could be most appropriate when deliberating over

what criteria all cases would need to meet (Patton, 2015). A systematic recruitment process could be employed to ensure patients meet the purposive criteria. The evaluator could utilise head injury clinical markers and screening instruments to support the selection of patients with suspected TBI (Wiklund et al., 2011).

When conducting usability testing with staff the use of a standardised patient is typically employed (Wiklund et al., 2011). The standardised patient is essentially an actor who can simulate neurological impairment through a standardised script (see appendix I for standardised patient character summary)(Patton, 2015).

A case finding tool for detecting TBI could be regarded as non-gender specific (Wiklund et al., 2011). Therefore, an equal distribution of female and male participants is required to determine whether there are gender differences when interacting with the health application (Tullis and Albert, 2013).

4.8 Phase four: Evaluate design solutions through data analysis

4.8.1 Qualitative analysis method

Usability evaluation research has clear guidance in how to plan and implement investigations. Unfortunately, the literature does not provide instruction in how best to analyse the usability data (Folstad et al., 2012). Analysis in usability research is the process of capturing rich problem descriptions of usability issues incorporating causes, implications and solutions. There are many usability evaluation techniques discussed within the literature. Few studies have explored the application of analytic methods in usability evaluation (Howarth et al., 2009, Kjeldskov and Stage, 2004). However, an exploratory study by Folstad et al. (2012) investigated how usability professionals applied analytic methods. Analysis of usability data was found to be informal and pragmatic (Folstad et al., 2012).

Applying usability evaluation in healthcare research presents a challenge when there is an absence of understanding in how to apply analytic methods to usability data. The following qualitative methods were considered; grounded theory (Charmaz, 2011, Glaser and Strauss, 1967) and thematic analysis (Braun and Clarke, 2006).

Grounded theory enables the exploration of a specific phenomenon and is concerned with the construction of theory from qualitative data (Charmaz, 2011). In social constructionist grounded theory, the process follows systematic guidelines for the collation, synthesis, analysis and conceptualisation of qualitative data leading to a theoretical account (Willig, 2013). It is not just an analytic method, it is an approach to qualitative research. Grounded theory perhaps is most appropriate to addressing research questions relating to social mechanisms which underpin a particular phenomenon (Glaser and Strauss, 1967). There are many examples of usability research studies which rely upon grounded theory to investigate human centred design topics (Ferreira et al., 2007, Fox et al., 2008, McInerney and Maurer, 2005, Matavire and Brown, 2008).

An objective of this study was to identify usability problems and generate ideas for redesign. In grounded theory, the intent is to achieve a higher level of conceptualisation which is unnecessary for this usability study (Glaser and Strauss, 1967). Usability research is perhaps more interested in a phenomenon as it appears within the data set which is an analytic strategy supported by thematic analysis (Braun and Clarke, 2006). Thematic analysis offers greater accessibility in the method's application and is less demanding of time (Aronson, 1995). Historically, thematic analysis has been poorly defined (Braun and Clarke, 2006). Aspects of thematic analysis have been found in grounded theory (Clarke and Braun, 2013). Braun and Clarke's (2006) six phase thematic analysis offers the theoretical flexibility required for this study. A description of the qualitative six phase model is provided:

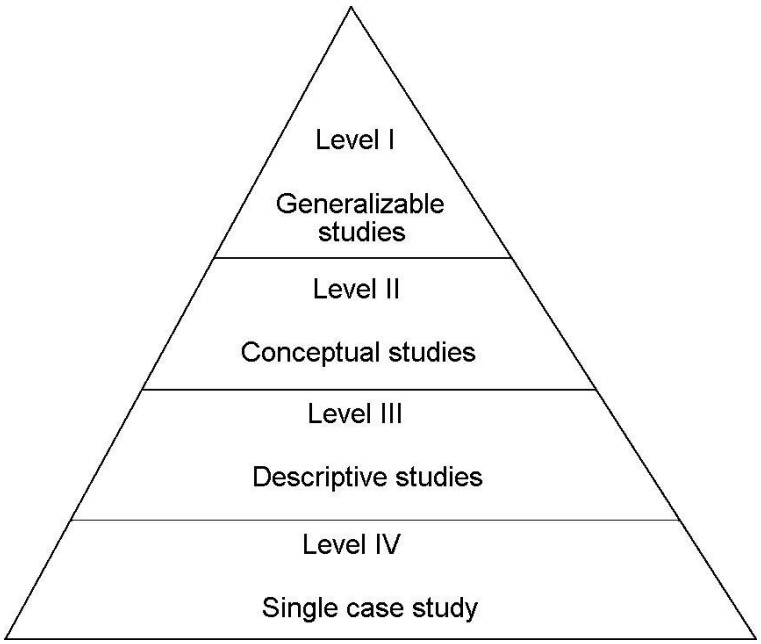
- Phase one: transcript data is reviewed searching for meanings and patterns
- Phase two: open codes are generated for data extracts
- Phase three: data extracts and codes are organised into initial themes
- Phase four: a thematic map is developed through linking codes and extracts across the data set
- Phase five: themes are defined and named with an overarching narrative
- Phase six: a narrative report is produced with illustrative extracts that represent the themes covered in the dataset.

  (Braun and Clarke, 2006)

Thematic analysis is exclusively an analytic method and not an approach to qualitative research (Braun and Clarke, 2006). Thematic analysis is not tied to data collection methods, theoretical positioning, epistemological or ontological frames of reference (Clarke and Braun, 2013). It has the capacity to answer most research questions and the method can be bottom up data driven, which is an important analytic feature for formative usability research and problem discovery (Aronson, 1995). Formative usability design and evaluation studies rely upon participatory approaches and this is possibly the greatest strength of Braun and Clarke's (2006) six phase analytic model as it is accessible and supports participants in having a role in the analysis of the data (Braun and Clarke, 2006).

The criteria for evaluating the trustworthiness of qualitative data has been a topic of much debate (Ali and Yusof, 2011). Critically appraising the trustworthiness of qualitative research findings is an important feature of evidence informed enquiry. A hierarchy of evidence for qualitative methods in healthcare has been developed and is illustrated in figure 3.

Figure 3- Qualitative hierarchy for evidence



(Daly et al, 2007, pg45)

Discussion will be limited to the appraisal of descriptive studies to complement the predominant method of enquiry used in this study. Descriptive studies are typically used to describe participant views with a concurrent research design (Daly et al.,

2007). The use of an independent auditor in data analysis can increase reliability through reaching consensus over the qualitative findings (Weber, 1990). To further enhance credibility the use of member checking could be incorporated into the analysis of the qualitative data. This would give participants the opportunity to clarify and confirm whether the data interpretation reflects their views (Russell and Gregory, 2003).

4.8.2 Quantitative analysis method

The analytic techniques applied to the usability data is dependent upon the question under investigation (Frokjaer et al., 2000). There are emerging studies which consider analysis in the context of redesign and it could be that such an approach would have more relevance in practical application (Hornbæk, 2010).

One of the most popular methods of analysing usability problems is counting unique usability issues (Tullis and Albert, 2013). Analysing the frequency of usability data provides a rudimentary understanding of usability changes between each design iteration. A reduction in detected usability problems between design iterations is not necessarily indicative of improvement between designs (Tullis and Albert, 2013). It is feasible a small number of usability problems could be highly detrimental to the health application's usability (Wiklund et al., 2011). By combining severity rating scales with usability frequency counting, it is possible to determine how often the observed issue reoccurs and establish whether high priority usability issues are being addressed between each design iteration (Wiklund et al., 2011). Basic analytic techniques can offer considerable insight using averages and standard deviations (Wiklund et al., 2011). Descriptive statistics are frequently used to summarise usability data and highlight measures of central tendency (Hornbæk, 2010).Rubin and Chisnell (2011) provide an analytic method in which frequency and severity can be combined.

Frequency is calculated by the percentage of total participants affected by the usability problems and is ranked on a four point scale (see table 3) (Tullis and Albert, 2013).

Table 3- Frequency and severity Likert scales

Rating Score	Frequency Criteria	Severity criteria
1	Occurs less than 10% off the time	Usability problem causes mild irritation
2	Occurs between 11% and 50% of the time	Usability problem causes moderate issues
3	Occurs between 51% and 89% of the time	Usability causes severe issues
4	Occurs at least 90% of the time	Usability problem makes the product unusable

Severity of usability problems is rated on a four point ordinal scale. A criticality score is achieved by combining the frequency and severity rating scores (Tullis and Albert, 2010). Usability priorities can be predefined and categorised in line with the objectives of the usability study (Rubin and Chisnell, 2011).

4.9 Ethics

Ethical consideration is the process of anticipating and resolving ethical dilemmas throughout all stages of research rather than rigidly following guidelines set by a professional body. The Belmont Report (NCPHSBBR, 1978) outlines three core ethical guidelines; autonomy, beneficence and justice.

4.9.1 Autonomy

The ethical principle of autonomy acknowledges the need to be sensitive to the issue of gaining consent and the right not to participate in the study (Marshall, 2006). The impaired capacity of participants with comorbidity presents a challenge for autonomy when obtaining informed consent (Drane, 1984). For participants with co-occurring substance use disorder (American Psychiatric Association, 2013) and neurological disability cognitive restrictions can increase complexity when attempting to gain true consent and enable decisional freedom (Faden and Beauchamp, 1986).

The issue as to whether comorbid participants have the cognitive capability to comprehend the research topic and participate in research is controversial (Drane,

1984). Substance dependence and neurological disability severity can vary markedly across the treatment population (Compton et al., 2007). The co-occurring disorders could cause transient loss of capacity (Tarter et al., 1995).

There is a need to evaluate the decisional capacity of different treatment populations consenting to take part in research (Drane, 1984, National Bioethics Advisory Commission, 1998). Incorporating understanding of disclosed information, comprehension of the research significance, capability of using information in reasoning and the ability to state a clear choice (Flaskerud and Winslow, 1998). Target population peer review is one method utilised by researchers. Patient expert reference groups can appraise consent form content and levels of understanding can be determined by researchers (Strauss et al., 2001). To avoid ambiguity or misunderstanding the purpose statement of the research must be clear to participants so there is no confusion over the intent of the research study (Strauss et al., 2001).

4.9.2 Beneficence

Beneficence is the principle of ensuring the chosen research topic ultimately benefits the target population and does not contribute to marginalisation or disempowerment (Haverkamp, 2005). The priority for beneficence is to reduce harm and provide benefits to the treatment population under investigation (Emanuel et al., 2000). There is a moral imperative for researchers to ensure vulnerable participants benefit from their research participation (Ruof, 2004). For patients with substance use disorder and neurological disability receiving drug and alcohol treatment the issue of burden becomes a higher priority (Sarantakos, 2012). The ethics review panel will need to see evidence that steps have been taken to minimise the burden for participants with co-morbidities (Ruof, 2004).

In usability studies, cognitive walkthrough is a frequently used evaluation method by researchers (Polson et al., 1992, Wharton and Lewis, 1994). The process of encouraging participants to think aloud is increasingly viewed as a moral enquiry (Flick, 2009). Consideration needs to be given to participant exposure to stress which could be exasperated with vulnerable co-morbid populations (Creswell, 2009). Low tolerance

to stress, poor concentration and difficulties with problem solving are all indicative characteristics for participants with brain injuries (Ardila, 2013). It is difficult to anticipate harmful disclosure from participants and dysexecutive syndrome increases the likelihood this will occur with a neurologically impaired research population (Ardila, 2013). Protecting the participant's privacy through ensuring anonymity is essential (Patton, 2015). Participant names can be disassociated from transcripts during the coding process of data analysis (Creswell, 2009). Data storage, disposal and ownership are all important considerations and need to be fully resolved within the ethical review application (Creswell, 2009).

4.9.3 Justice

The principle of justice acknowledges how the burden and risk of participating in research should be shared equally amongst the treatment population who stand to benefit from the investigation (Punch, 2013). Justice recognises how research participants who are economically, socially, biologically and legally disadvantaged are more vulnerable to research pressure (NCPHSBBR, 1978). Special vulnerability is categorised as lack of capacity to consent to research and increased likelihood of coercion and harms (Lange et al., 2013).

Patients with comorbidity are frequently subject to coercion from criminal justice services to participate in drug and alcohol treatment (Sarantakos, 2012). The pressure to participate in research can be viewed as existing on a continuum ranging from persuasion to coercion (Emanuel et al., 2000). Research oriented more towards coercion is less ethical (Faden and Beauchamp, 1986). The burden of participation should be offset against the gain in scientific understanding, from which the participating population should directly benefit (Faden and Beauchamp, 1986).

4.9.4 Ethics in mixed methods research

Ethical consideration for mixed methods research typically encompasses more complexity (Andrew and нalcomb, 2009). The qualitative researcher enters the lives of the participant even when the contact is brief with in-depth semi structured interviews. This generates several ethical and strategic dilemmas which are perhaps not found with quantitative research (Locke et al., 2013).

The preparation of the research proposal should incorporate two types of data collection methods (Mertens, 2014). There are many ethical issues prevalent within the data collection stage of research (Creswell, 2009). Recruitment, sampling strategy, data collection instruments and the analysis of data sets need to be considered from both qualitative and quantitative perspectives (Andrew and нalcomb, 2009).

The nature of the study should determine whether the ethics application integrates both data collection methods in a single proposal or the two arms of the study are provided in separate applications (Mertens, 2014). For a mixed methods study where there is a concurrent research design a single application would be preferable (Creswell, 2009). Conversely, for a sequential design where each method of data collection is conducted separately two applications may be more appropriate (Mertens, 2014).

The ethics proposal needs to explicitly demonstrate the rationale for mixing both qualitative and quantitative data sets. This is an important consideration as there is the potential to increase the burden to participants by collecting two data sets (Creswell, 2009).

Participants with neurological disability are more susceptible to fatigue and steps should be taken to reduce the burden of participation (Andrew and нalcomb, 2009). A concurrent mixed methods design could be used to minimise burden as quantitative data could be extracted from qualitative transcription post usability testing.

Furthermore, repetitive or seemingly meaningless questioning can contribute to the experience of fatigue and should be avoided where feasible. Test administrators

should be sensitive to the initial signs of fatigue and respond accordingly by ensuring there is opportunity to take breaks or end the test prematurely. The usability test environment should be designed to accommodate the needs of participants with a limited attention span.

A further challenge to data collection is negotiating access to research sites and the target population. The proposal must demonstrate the mechanism by which site permission will be obtained. Researchers who are authentic, enthusiastic and embody a genuine interest in the research site should have a comprehensive understanding of formal and informal gatekeepers to the organisation (Marshall, 2006). Site permission will be obtained ensuring minimal disruption and organisational guidelines for conducting research are adhered to (Creswell, 2009).

4.10 Reflexivity

Reflexivity is the critical exploration of the researcher's subjectivity (Somekh and Lewin, 2005). Bias is inherent throughout every stage of the research process as the researcher designs the study, collects the data and interprets the findings (Gerrish and Lacey, 2010). Transparency is valued when building trustworthiness in the research process (Mertens, 2014). Awareness of impact on data collection enhances an understanding of data interpretation. This section brings together five strands which have influenced this topic of investigation:

- my lived experience of disability
- designing through necessity
- formal training in counselling psychology
- work based experience in community drug and alcohol treatment
- published work

I never considered myself to be a designer. In fact, I believed I was devoid of any creative ability whatsoever. Thus, it would seem a research topic on user centred design and evaluation would not be an obvious choice for me. That is until 20 years ago, when life gave me a shift in perspective. My sight started to deteriorate and the need to adapt became an urgent reality. These new life skills set the foundation for

designing through necessity. At the time, I was training to become a counselling psychologist and honing my skills as an empathic therapist. Unbeknownst to me these two life skills of problem solving and empathy would shape my future research interests. Now I am registered blind and I have frequently heard myself complaining how this world has not been designed with me in mind.

Designing for disability captured my interest and formed the rationale for this study. Human centred design and evaluation is a method by which you can capture the unique lived experience of people with disability. There are many examples of technological advancements which were initially designed for people with impairments and are now enjoyed by the mainstream. Screen readers, voice recognition and text messaging are a few good examples.

Fortunately for me, design skills are something which can be learnt. Empathic design is at the heart of this study through following human centred design and evaluation principles. Valuing the experience of the end user through an empathic enquiry was a natural ontological step for me. Over 16 years' experience in community drug and alcohol treatment services has influenced my pragmatic leanings creating the conditions for a research topic which embraced methodological pluralism. In my earlier published work with patients who experienced co-occurring mental health disorders and addiction the issue of impaired working memory kept reoccurring (See appendix J for publications)(Delgadillo et al., 2011, Delgadillo et al., 2012a, Delgadillo et al., 2012b, Delgadillo et al., 2015, Gore et al., 2015). A review of the literature revealed how depression and anxiety in combination with substance use disorder was a clinical marker for traumatic brain injury. Neurological disability in patients receiving drug and alcohol treatment in the UK has received minimal attention and formed the basis for the research question under investigation.

4.11 Conclusion

In conclusion, this chapter has provided an explanation for the adoption of pragmatic methodology in a human centred design and evaluation study. The mixed methods paradigm complements formative usability research methods. Concurrent embedded

mixed methods design offers an approach used in software development. Planning a usability study needs to be a collaborative and inclusive process involving end users and stakeholders. Literature review and stakeholder involvement could establish context of use and understanding of patient and staff requirements from a head injury survey application.

To ensure inclusivity for stakeholders with neurological deficits paper based prototyping in combination with usability guidelines could make abstract design concepts more tangible. Evaluating design solutions for a prototype head injury survey user interface requires a sample which has credibility. Purposively recruiting patients and staff who have lived and practice based experience could enhance the detection of usability problems. Cognitive walkthrough and problem discovery techniques are useful usability evaluation methods for early instrument development when the type and scope of usability problems are unknown (Sauro and Lewis, 2016). Wider usability literature offers minimal guidance in the application of analytic methods for qualitative and quantitative data types. The usability industry has adopted a pragmatic approach to data analysis. Thematic analysis and basic descriptive statistics offer the theoretical flexibility required for formative usability research. Ethical consideration was given in seeking consent and minimising burden with vulnerable patients. Designing for disability using human centred principles through valuing lived experience and evidence informed guidance formed the basis for this study.

5.0 Method

5.1 Introduction

This chapter outlines the process underpinning this formative human centred design and evaluation for early instrument development (Nieveen and Folmer, 2013). The identification and recruitment procedure for key stakeholders is provided. Detail in how discussion groups adhered to usability guidelines in paper based user interface development is offered (Snyder, 2003). Choices in hardware, cyber security and decision support software are discussed and health context of use defined. The mixed methods research design, recruitment procedure, sample size and analytic methods are provided (Wharton and Lewis, 1994, Rubin, 1996). The chapter concludes with ethical considerations for the implementation of the study.

5.2 Human centred design and evaluation in health application development

In human centred design and evaluation, it is crucial to involve patients and staff throughout the design, evaluation and development process (Rubin and Chisnell, 2011). The rationale for this is to capture patient and staff perspectives of what could be useful for the target population, at risk patient groups and associated health and social care professionals (Wolpin and Stewart, 2011). To increase the credibility of the health application the involvement of patients and staff as content experts was evidenced throughout the design and evaluation process (see appendices J and K)(Fromme et al., 2011).

Building links with the target population was a fundamental step to take when creating a design space which generates an exchange of ideas and design solutions (Fromme et al., 2011). In developing a health application user interface the four human centred design and evaluation phases were adhered to

- context of use
- specify the patient and staff requirements
- produce design solutions
- evaluate designs

(ISO, 2010)

The human centred design and evaluation four phase process has been expanded upon throughout this chapter.

5.3 Phase 1: Context of use

One of the first key considerations that occurred in the planning of the formative evaluation study was defining the context in which the health application was evaluated (Thomas and Bevan, 1996). The setting was a community drug and alcohol treatment service. The service provides access to medical care, structured care coordination and psychosocial interventions as per national treatment guidelines for patients with substance use and alcohol problems. Approximately 500 patients engage with the service per annum seeking treatment and support for a variety of substance dependence issues. Complex social problems are pervasive in this population, which require the team to work closely with child social care, criminal justice, mental health, housing, education, and employment support services. The intended user population for the head injury survey application was patients and staff in this service. It was anticipated patient end users may well have low reading ability and cognitive restrictions (Williams, 2012). Types of neuro-deficits might include impaired working memory, limited attention span, reduced capacity to attend to multiple streams of information or problems with executive functioning (Williams, 2012).

5.3.1 Patient and staff stakeholder expert reference groups

The service user involvement network is a patient led group which has professional observers. The group is a collaboration between a dual diagnosis network and a service user involvement forum for health and social care services. There are approximately 11 members with a range of statutory and voluntary sector, mental health and substance use experiences. The service user involvement network remit is to promote patient involvement through valuing personal expertise, with the intention of shaping strategic development and improving access to service provision for people with complex needs.

A patient expert reference group was formed from interested members from the service user involvement network. To take part in the patient expert reference group,

members were required to have a dual diagnosis for common mental health disorder and substance use disorder (American Psychiatric Association, 2013). This served as a clinical marker for multiple traumatic brain injury (TBI) (Walker et al., 2007). Person related demographics such as age, race and gender were important but deemed secondary to the identified clinical markers. The research proposal was presented at the service user involvement network. Following the presentation any interested members were contacted via telephone within 1 week by the principle investigator. Four patient members were recruited for the stakeholder expert reference group in line with usability guideline recommendations (US Department of Health and Human Services, 2006).

The research proposal was presented at the community drug and alcohol treatment service clinical team meeting. Following the presentation any interested staff were contacted via email within 1 week by the principle investigator. Four staff working in the community drug and alcohol treatment service from a multidisciplinary team of 25 who had direct clinical contact with at risk patient groups for TBI were recruited for the staff stakeholder expert reference group.

5.4 Phase 2: Specify the patient and staff requirements

There are established evidence informed design and evaluation guidelines for health technology application development (US Department of Health and Human Services, 2006). Good practice recommends showing how the design and evaluation method uses the recommended guidance (Fromme et al., 2011, Stoddart et al., 2006). In this study guidelines were adhered to in the development of the health applications user interface (US Department of Health and Human Services, 2006).

Data was collected from patients and staff and recorded in expert reference group minutes (see appendix K and L). A discussion group was considered a useful method for an investigator who needed to retain control over the line of questions when following structured usability guidelines (Creswell, 2009).

5.5 Phase 3: Produce design solutions

The stakeholder involvement consultation period was conducted over five months in 2013. Two stakeholder expert reference groups were formed, one consisting of patients and the other, staff. In total, patients held five stakeholder meetings and staff held two stakeholder meetings. The principle investigator and research assistant delivered a series of presentations on parallel design, page layout and navigation to both stakeholder groups (presentation scripts and slides can be found in appendices L and M).

The stakeholder expert reference group members were set the task of generating their own independent design ideas for adapting the OSU TBI-ID (Corrigan and Bogner, 2007). Stakeholder expert reference group members generated several concepts using the best elements from each idea, referred to as parallel design (US Department of Health and Human Services, 2006). This helped identify the challenges placed upon the target population in terms of cognitive demand in completing the head injury survey application tasks and characteristics (Peute et al., 2008).

The stakeholder expert reference group members produced six iterations of the paper based prototype head injury survey refining content, terminology, page layout and navigation. The final stage in stakeholder expert review culminated in the approval of the head injury survey application prior to formative usability testing. All stakeholder expert reference group members unanimously approved the web-based head injury survey application.

5.5.1 Technical expert

A technical expert from the University of Leeds provided consultation in relation to clinical decision support software and cyber security (see sections 5.5.2 and 5.5.3)(please refer to expert reference groups minutes 12th July in appendix K). In making the transition from a paper based prototype to a digital instrument, increased consideration was given as to how the head injury survey application collected and processed patient data.

5.5.2 Clinical decision support software

A rule based decision algorithm for detecting TBI was defined (Atkinson, 1997). Converting tacit knowledge into a clinical decision support software required an understanding of the cognitive processes held by the trained professional when diagnosing TBI. Cognitive continuum framework was used to increase the principle investigator's cognisance when diagnosing TBI (Cader et al., 2005). Determining the mode of cognition used when detecting TBI was the first step in increasing cognisance (Hamm, 1988). There are three dimensions associated with modes of cognition; analysis, intuition and quasirationality (Hamm, 1988, Hammond, 1996). The cognitive mode of analysis has been defined as slow, conscious and consistent, conversely intuition is rapid and unconscious (Hamm, 1988). Quasirationality adopts elements of both analysis and intuition and occupies a central point along the continuum (Hammond, 1996).

Detecting TBI in patients receiving drug and alcohol treatment was a complex task. Screening for comorbidities required multiple clinical judgements and was an analytic process demanding a high degree of certainty (Hamm, 1988). This was achieved by the principle investigator securing an honorary clinical placement in a neuropsychology and rehabilitation team for adult patients with acquired brain injury. To increase cognisance the principle investigator received training in how to conduct neuropsychological assessments with TBI patients and co-occurring disorders. Detecting TBI required the identification of evidence informed clinical markers. For example, trauma to head or neck resulting in loss of consciousness with persistent neurological deficits. The OSU TBI-ID was broken down into four components. :

- Exposure to TBI throughout lifetime
- TBI clinical markers
- Medical care received and/or remaining neuro deficits
- Survey outcome

The OSU TBI-ID was adapted through the inclusion of the Department of Health clinical guideline for Head Injury: Assessment and early management (NICE, 2014). Pre hospital assessment head injury risk factors (NICE, 2014) were incorporated in

response to the 30% of substance using patients who do not seek medical care following a head trauma event (Corrigan and Bogner, 2007).

Detecting TBI was a systematic analytic process and required a high degree of certainty (Hammond, 1996). The clinical algorithm asked the patient a series of questions related to their exposure to head injury over a lifetime and presenting problems and symptoms. Depending upon the patient's responses the staff member was provided with the following diagnostic information; whether a head injury had been detected, the age at which the head injury occurred, the severity of the head injury and whether there were any remaining cognitive, emotional, behavioural or physiological complaints associated with head injury. Finally, the decision support software evaluated patient specific data and made a judgement on the extent to which the staff member could rely upon the accuracy of the detected head injury test result.

5.5.3 Operating system and cyber security

There are many available operating systems, however, the market is currently dominated by two platforms; Google Android and Apple iOS (NHS Innovations South East, 2014). Mobile devices operating systems are frequently upgraded to capitalise upon emerging hardware mobile technologies (Heitkötter et al., 2013). Developers need to account for the issue of backward compatibility or release new application updates (Bellifemine et al., 2008). Apple provide a software development kit and any new applications released on the 'App Store' need to be digitally certified by Apple (Bergvall-Kåreborn and Howcroft, 2011). Google's Apache licence is open source and the open source code can be modified by mobile device manufacturers and interested developers with certification (Misra and Dubey, 2013).

The instrument needed to collect sensitive personal data and safeguards were taken to ensure cyber security. Android was more vulnerable to cyber-attack in comparison to iPhone as the android platform is open source (Misra and Dubey, 2013). Risk to cyber security was mitigated through following the technical expert recommendation to use a customisable survey software application (Snap Mobile Anywhere). The licensed survey software offered data security through having a password protected

synchronous connection to a secure remote server database. Other open source development tools were available; PhoneGap and Appcelerator (Hartmann et al., 2011). However, the technical skill required to use these applications was beyond the skill set of the research team and so discounted.

The hardware selected to conduct usability testing was chosen based on the availability of the technology in a community drug and alcohol treatment service. Hardware system specifications can be found in tables 4 and 5.

Table 4- Samsung Galaxy Tab 2 7.0 (WiFi)

Platform	
Operation System	Android 4.0 (Ice Cream Sandwich)
Browser	Android Browser
Design	
Form Factor	Tablet
Physical Specification	
Dimension (HxWxD)	122.4 x 193.7 x 10.5mm
Weight	341g
Display	
Technology	PLS TFT LCD
Resolution	1024 x 600 (WSVGA)
Size	7.0"
Music & Sound	
Music Player	Supported Codec: MP3, OGG, AAC-LC / AAC / AAC+ / eAAC+, AC-3, AMR-NB / WB, WMA, WAV, MID, IMY, FLAC
3D Sound Technology	3D: Earphone / Speaker both
Music Library	Sound Alive solution powered by Samsung
Connectivity	
Bluetooth	BT 3.0
USB	USB 2.0 Host
Internet HTML Browser	Yes
SyncML (DS) Support	OMA DATA SYNC 1.2
SyncML (DM) Support	DM 1.2, FOTA
WiFi	802.11b/g/n, WiFi Direct
PC Sync Application	Samsung Kies
Memory	
External Memory	Up to 32GB
Further Information	
Touch Screen	C-Type

Table 5- LENOVO H30 Desktop PC

Platform	
Operation System	Windows 10 (64-bit)
Design	
Form	PC
Physical Specification	
Dimension (HxWxD)	308 x 105 x 399 mm
Weight	5.9 kg
Display	
Technology	LED-backlit LCD monitor
Resolution	1366 x 768 at 60 Hz
Size	19"
Music & Sound	
3D Sound Technology	3.5 mm jack
Connectivity	
Bluetooth	N/A
USB	- USB 3.0 x 2 - USB 2.0 x 4
Internet HTML Browser	Yes
WiFi	802.11 b/g/n
Memory	
External Memory	7-in-1 memory card reader
Further Information	
Storage	1 TB HDD, 7200 rpm
Memory (RAM)	8 GB DDR3 (16 GB maximum installable RAM)

5.6 Phase 4: Evaluate designs

The paper based prototype adapted from the OSU TBI-ID (Corrigan and Bogner, 2007) was digitised using Snap Mobile Anywhere (Snap Surveys Ltd, 2016). The formative usability objective was to conduct an evaluation of the prototype user interface for a

TBI case finder with patients and staff in a community drug and alcohol treatment setting through the identification of usability problems and idea generation for redesign. A concurrent embedded design was used for instrument development (Johnson and Onwuegbuzie, 2004) and the mixed methods paradigm emphasis was predominantly qualitative (Morse, 1991). Time ordering of methods was concurrent with a pragmatic theoretical orientation. A process of abductive reasoning was used through converting usability observations into rich problem descriptions (Morgan, 2007). The rationale for this was to use the qualitative findings to inform the problem discovery redesign priorities (Greene et al., 1989).

5.6.1 Calculating sample size

There was no formal sample size calculation as this was a formative usability study (Rubin, 1996). However, the available literature on determining sample size for formative usability studies recommend that four participants per group ensured a 94% likelihood of detecting at least once usability problems that have a probability of occurrence of 0.5 (Sauro and Lewis, 2016, Tullis and Albert, 2013).

5.6.2 Patient formative usability recruitment

- The principle investigator conducted a briefing at the community drug and alcohol treatment service clinical team meeting introducing the study purpose and recruitment strategy. A copy of the patient information leaflet (appendix O) was provided.
- Patients who reported using substances or opiate substitute treatment within the last month, and who scored 12 or below on the Treatment Outcome Profile psychological rating scale were asked to consider taking part in the study after receiving a participant information leaflet. Permission was requested to forward their contact details to the principle investigator to discuss the study in more detail and to clarify any questions or concerns. Note that this did not yet constitute consent to take part in the study.
- Potential participants who expressed interest were contacted via telephone within one week by the principle investigator to discuss the study. Staff informed the principal investigator over frequency of patient refusals to take

part in the study. Signed consent forms were returned personally or via post to the principle investigator.

5.6.3 Staff formative usability recruitment

- Principal investigator circulated email request for community drug and alcohol treatment service staff to take part in usability study and provided clinician information leaflet (see appendix P).
- Community drug and alcohol treatment service staff forwarded their expression of interest in study via email to the principal investigator. Any interested staff were contacted via email within one week by the principal investigator.
- Principal investigator obtained informed consent.
- Principal investigator arranged for participants to undertake usability testing of prototype head injury survey application.

5.6.4 Patient inclusion criteria

Patients were eligible to participate in the formative usability test if they:

- Were engaging with a community drug and alcohol treatment service. Engagement was defined by (a) registered with a community drug and alcohol treatment service and (b) had planned contact with the service within the last month.
- Had a score of 12 or below on the Treatment Outcomes Profile (TOP) (Marsden et al., 2008) psychological rating likert scale for common mental health disorders (87% probability of detecting common mental health problem) (Delgadillo et al., 2012a).
- TBI detected using the Brain Injury Screening Index (BISI) (Pitman et al., 2015).
- Had used alcohol, drugs, or opiate substitute treatment within the last month

5.6.5 Patient exclusion criteria

Patients were not eligible to participate in the formative usability test if they:

- Were not engaging with a community drug and alcohol treatment service

- Did not meet the threshold for the clinical marker as defined by TOP (Marsden et al., 2008) psychological rating likert scale for common mental health disorders
- TBI not detected using BISI (Pitman et al., 2015)
- Were free of substances of dependence, including opiate substitute treatment
- Did not have mental capacity (Department for Constitutional Affairs, 2003)
- Were not an English language speaker

5.6.6 Staff inclusion criteria

Staff were eligible to participate in the formative usability test if they were working within a community drug and alcohol treatment service in a clinical role. A clinical role was defined by a member of staff who had direct contact with patients and conducted TBI screening.

5.6.7 Qualitative – cognitive walkthrough

A cognitive walkthrough method was used focusing on participant's cognitive processes when interacting with the head injury survey application (Wharton and Lewis, 1994). Participants were given the opportunity to identify user interface usability barriers and difficulties with navigation, content, page layout, terminology, data entry and technology. Participants could provide comments on how the design structure worked together (Andre et al., 2003). The cognitive walkthrough made it feasible to understand diagnosed problems, elicit recommendations, evaluate product design and measure participant satisfaction.

The test administrator conducted the cognitive walkthrough usability test. The test administrator followed a set script with each participant which can be viewed in appendix Q. The usability test required specific apparatus; audio digital recorder, tablet computer and personal computer. The audio recordings were transcribed verbatim. A cognitive walkthrough procedure was followed developed by Wharton and Lewis (1994).

When conducting usability testing with staff the addition of a standardised patient was employed (Guise et al., 2012). The standardised patient was an actor who simulated neurological impairment through following a standardised script (Guise et al., 2012).

5.6.8 Quantitative – problem discovery

Unique usability issues were counted and severity was rated using Rubin's (1996) issue based metrics. Frequency and severity were ranked using four point likert scales. Frequency was determined by the identification of unique usability problems across five predefined categories; terminology, navigation, content, page layout, data entry and technology. Each category represented a proportion of identified usability problems across the two affected groups, patients and staff.

Usability criticality score was achieved by combining frequency and severity rating scores and had a range of between two and eight, the higher the score the greater the redesign priority (Rubin and Chisnell, 2011).

5.7 Usability test environment

The evaluation was conducted in a consulting room used by staff within the community drug and alcohol treatment service. To help ensure confidentiality and prevent distraction from background noises the room had sound insulated walls. The dimensions were approximately 3.5m x 4m. Furniture consisted of two comfortable chairs and one low coffee table. There was a single entry point with a sliding notification sign designating the room as free or engaged. This helped minimise unforeseen interruptions which could have disturbed the test environment. The floor was carpeted and the walls had a neutral decoration. There was a large window fitted with vertical blinds to control ambient light levels. The room was equipped with a panic alarm which could be triggered in the event of a crisis. There was an assigned member of staff who was available based at the duty desk near reception who could respond to the alarm and provide support.

5.8 Qualitative - thematic analysis

The qualitative analytic strategy complied with Braun and Clarke's (2006) six phase analytic model.

Phase 1: Qualitative data analysis was carried out by the principle investigator who independently reviewed the eight transcripts searching for meanings and patterns. This was achieved through the process of immersion in the qualitative data set and salient notes of interest were recorded. Meaning was derived through active familiarisation and critical analysis of the textual data (Braun and Clarke, 2006).

Phase 2: The pre-analytic process of selective coding was used to pragmatically identify the predefined areas of interest; content, terminology, page layout, navigation, data entry and technology. This reductive data driven approach involves a degree of analysis through the identification of predefined analytic concepts (Braun and Clarke, 2006). Semantic codes were captured recording explicit content generated by participants reflecting their language and concepts. The research question framed the systematic coding process capturing concise and relevant codes. Data extracts from complete coding were collated in Excel.

Phase 3: Pattern based analysis was conducted identifying reoccurring ideas across the dataset. Relevance of patterns was not just limited to their frequency, but extended to their meaningfulness in connection to the research question. Candidate themes were developed through the organisation of ideas into a central concept. All the relevant coded data was collated and themes were actively constructed. This process involved capturing salient patterns relevant to the research question and discarding themes which did not meet the best fit of analysis.

Phase 4: A thematic map was produced reviewing the relationships between linked codes and themes across the dataset. Themes were retained if they reflected the richness and depth required for a central concept in the data. The codes were revisited to evaluate whether they worked with the candidate theme. Once the revised themes had a distinct central organising concept which related to the research question, the

un-coded dataset was revisited repeatedly ensuring the revised themes captured the topic of enquiry.

Phase 5: The completion of a satisfactory thematic map led to the preparation and further revision of themes for analysis. This was achieved through defining each theme and refining the content. Data extracts were identified which were interesting and relevant to the topic of enquiry. Each theme was interpreted and linked to the broader narrative. Sub themes were used to provide structure to larger complex themes.

Phase 6: The deep analytic interpretative analysis of identified patterns commenced in the writing of the report producing a coherent and compelling story. Each theme was defined providing a plausible explanation. Extracts were identified which best illustrated the different aspects of each theme, demonstrating breadth and spread across the data. Data was cleansed by the removal of hesitation and repetition. Unnecessary details were deleted and indicated in the extract by '(…)'. Punctuation was included to enhance readability and not change the meaning of the extract. Each participant was assigned a data ID code and a key was provided. Illustrative extracts were used to support the analytic narrative. Themes were interpreted and a narrative constructed, driven by the research question. Candidate themes underwent further minor revisions as the analysis informed the development of the narrative (Braun and Clarke, 2006).

To ensure analytical robustness the research team independently reviewed the themes (SG, JB and GN). SG independently conducted open coding for phases 1, 2 and 3. Iterative data analysis meetings were held for phases 4, 5 and 6 with the wider research team. A thematic narrative was developed using Microsoft Excel to perform clustering of themes. It was not feasible to involve stakeholders with the analysis of anonymised data due to time constraints.

5.9 Quantitative – descriptive statistics

The usability data was quantitatively analysed using basic descriptive statistics. The two affected groups, patients and staff, underwent separate problem discovery

analysis using Rubin and Chisnell (2011) issue based metrics rating scales. A frequency count of unique usability problems was completed across the five predefined usability categories which were selectively coded in the thematic analysis. Proportions were calculated from the identified unique usability problems within the five predefined usability categories across the two affected groups. A frequency rating score was assigned to each predefined category. The identified unique usability problems in the five predefined usability categories received individual severity rating scores and a mean average was calculated for each category and a severity rating score assigned. The frequency and severity scores were combined to achieve a criticality score for prioritising usability problems within the five predefined categories across the two affected groups. The following equation illustrates how the criticality score was achieved: Criticality = Severity + Frequency of Occurrence (Rubin and Chisnell, 2011).

5.10 Ethics

This study received favourable opinion from the NHS Health Research Authority NRES Committee Yorkshire & the Humber - Leeds West. REC reference: 14/YH/0139. (See Appendix R)

5.10.1 Participant consent

The study took the following steps to ethically obtain informed consent:

- To replicate what occurs in routine care it was considered most appropriate for recovery coordinators to screen for suitability. It was preferable for patients to make early disclosures about mental health (a clinical marker for TBI) in the context of a positive therapeutic relationship. It was important that an independent person who was not directly involved in the patient's care should obtain formal informed consent, so that patients did not feel pressured into agreeing to participate due to their relationship with their recovery coordinator. For this reason, recovery coordinators asked potential participants for permission to request the principle investigator made contact.
- It was important that patients had an opportunity to discuss and clarify any questions thoroughly before considering whether they wished to participate. A telephone conversation with the principle investigator ensured that patients

who may have had low reading ability would have been able to provide informed and considered consent. The principle investigator asked potential participants if they would like to think about the study and whether they wished to participate for one week before providing signed consent.

- Patients had the right to withdraw from the study at any stage and the right to request their data to be deleted from the study dataset.

5.10.2 Data handling and record keeping

Several measures were taken to protect participants' confidentiality and secure the study data:

- The principle investigator maintained an electronic register of patients who agreed to be contacted to discuss the study and provided informed consent or refused informed consent. This register was a general record of the study recruitment process and included patient names for contacting potential participants to obtain consent and to arrange usability evaluation. The names and contact details of patients who did not provide informed consent were deleted from the register. A numeric count was kept to record the numbers of people who refused to take part.
- Access to paper based files or data, except for signed participant consent forms which were securely stored in a locked cabinet in a single community drug and alcohol treatment service was limited. This cabinet was in a section of the building which was accessible only to staff.
- The principle investigator was responsible for collating a study database containing screening, usability evaluation, demographic and clinical data obtained during the recruitment and evaluation stages. The electronic database was stored in a secure network drive as described above.
- The dataset was fully anonymised and contained no personally identifiable details such as names, addresses, telephone numbers or email addresses.
- Encrypted USB memory cards were used strictly to store and transport data between NHS and university sites. Once data was transferred in this way, memory cards were erased.

- Transcripts from cognitive walkthroughs were stored as described above by the principle investigator at the community drug and alcohol service.
- Following the end of the study period (12 months), all strictly anonymous study data was stored in a secure network drive for a period of 5 years. This is compliant with the service's information governance policy which requires research data to be auditable by the University of Leeds. Any other copies of datasets held in the community drug and alcohol service were destroyed. The sponsor for this research study was the University of Leeds.

5.10.3 Distress strategy

Recovery coordinators and the research team directly interacting with patients may have become aware of distressing events in one of two ways:

- If the participant disclosed suicidal ideation or intent
- If the participant made any other disclosures that indicated potential risk to self or others.

5.10.4 Reporting and responding to distress

The recovery coordinator or research team member who became aware of a distressing event would:

- Take the appropriate action based on the nature of the distressing event. Any actions taken would have been carried out in consultation with the research team.
- Immediately report this to the principle investigator by telephone.
- Only if the research team became aware of a life-threatening event (suicide attempt) the principle investigator would have reported this to the representative of the sponsor organisation (University of Leeds) and the relevant contact person from the community drug and alcohol treatment service.

The procedure below stipulates the actions the research team would have taken if disclosures are made which raise serious concerns about risks to self or others:

- Provide participant a risk management and self-help leaflet which advises the participant on available sources of support; describe the leaflet information verbally via face-to-face contact or telephone.
- Ask participant for consent to contact their recovery coordinator at the community drug and alcohol treatment service at which they are registered.
- Remind the participant about the exceptions to confidentiality described in the patient information leaflet
- Inform the principle investigator by telephone.
- If the research team member has serious concerns (e.g. the participant discloses active suicidal plans and intent), the participant's recovery coordinator and GP will be informed immediately to take appropriate action. Participants will be aware this will happen from the outset of the study.

6.0 Results

6.1 Introduction

This chapter will present the findings of the formative usability evaluation. In making the transition from paper based prototyping to a head injury survey application, the instrument required the development of a clinical algorithm. Clinical decision support software can facilitate health and social care professionals in making evidence informed clinical recommendations for their patients (Dowding, 2002). The clinical algorithm embedded within the head injury survey application for this study was based upon the Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID) (Corrigan and Bogner, 2007, Bogner and Corrigan, 2009) and the Department of Health clinical guideline for Head Injury: Assessment and early management (NICE, 2014). Registered patients receiving community drug and alcohol treatment were recruited if traumatic brain injury (TBI) was detected using a standardised measure. The usability objective was to gain a better understanding of patient's usability needs when interacting with the head injury survey application with neurological disability and substance use disorder (American Psychiatric Association, 2013). The validity and reliability of the instrument was not evaluated in this study. Staff who have direct access to patients with TBI took part in the study and were able to provide feedback on the usability of the head injury survey application when working with patients with suspected neurological impairment (Please see section 6.2 Participants). The usability of the head injury survey application was evaluated by collecting both qualitative and quantitative research data concurrently (Creswell, 2013). The findings from the thematic analysis and problem discovery are presented.

6.2 Participants

Eight participants were purposively sampled to ensure relatively equal distributions of participants according to variables that distinguish between datasets, including whether they were a patient or staff member and by gender. The recruitment targets were n = 4 patient participants and n = 4 staff participants within 12 months. Therefore, the study recruited approximately 2% of the available patient population and 16% of the available staff member population.

For future design iterations it will be possible to use the initial findings from this study to assess whether the small sample size would be sufficient to identify the potential number of usability problems that exist (Sauro and Lewis, 2016). This would be achieved through calculating the average detection rate of usability problems per participant (Sauro and Lewis, 2016).

Eight participants completed usability testing (four patients and four staff), four of the participants used a tablet computer and four a personal computer. Most participants were White British (N = 7), with a mean average age of 42.6 years (range = 33 to 51). None of the four patients who were purposively recruited for the study were abstinent from substances at the time of registration and data collection. The most common reported substances used by this group were heroin (N = 2), crack cocaine (N = 2) and cannabis (N = 1). Only one patient was a poly-illicit substance user. None of the patients were alcohol dependent or used over the counter medication. The majority were prescribed opiate substitute medication (N = 3). Patients' mean score for the Treatment Outcomes Profile (TOPs) was 8.25 (range = 7-10) (Marsden et al., 2008). A score of 12 or below has an 87% probability of detecting common mental health problems, a clinical marker for detecting TBI (Wiklund et al., 2016, Delgadillo et al., 2012a). The mean number of head injuries was 2.5 (range = 2-3). An overview of patient characteristics can be found in Table 6.

Table 6- Patient characteristics, demographics, head Injury, mental health and substance use behaviour

Characteristics	**N**
Gender:	
Male (%)	2 (50%)
Female (%)	2 (50%)
Mean age (range)	40 (33-51)
Mean no. head injuries (range)	2.5 (2-3)
Mean TOPs Psychological health scale (range)	8.25 (7-10)
Substances used in the last month:	
Heroin	2
Crack	2
Cannabis	1
Cocaine Powder	1
Alcohol	1

Four staff members took part in the study. Two female and two male. Their mean age was 45.25 (range = 41-49). All staff who took part in the study had direct contact with patients receiving community drug and alcohol treatment and would have conducted TBI screening as part of their clinical role. Three case managers and one specialist addiction doctor completed usability testing with the prototype head injury survey application.

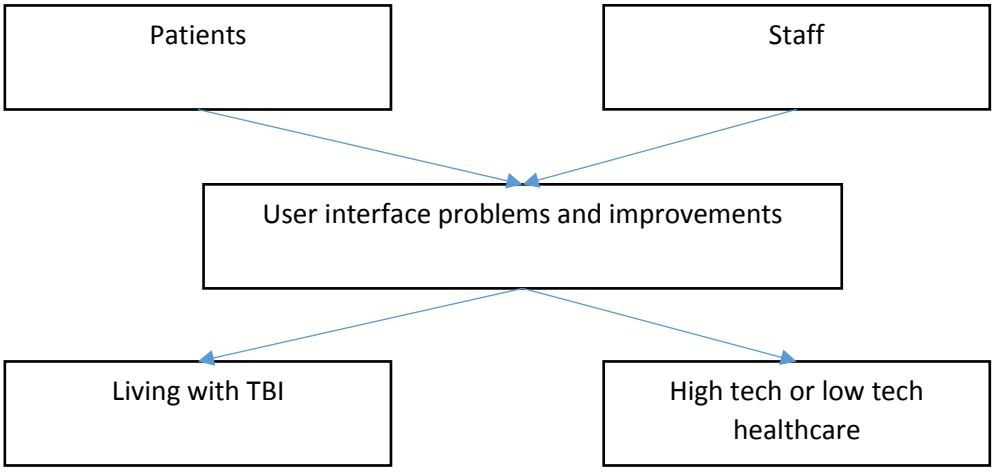
6.3 Stakeholder user interface design recommendations

It was not feasible to implement all of the design recommendations offered by the two stakeholder discussion groups. The software developer who was in the initial research team unexpectedly left the project leaving the principle investigator to make some pragmatic choices in how the study could be continued. A low cost application programming interface (API) was selected, Snap Mobile Anywhere (Snap Surveys Ltd, 2016), which meant a number of design recommendations could not be adopted. There were two limiting factors for the final digital user interface 1) the functionality of Snap Mobile Anywhere (Snap Surveys Ltd, 2016) and 2) the technical skill of the research team member when coding the application. Finally, the absence of an independent user interface reviewer to ensure the design recommendations had been implemented compromised the user interface design which underwent formative usability evaluation. The stakeholder expert reference group design recommendations can be viewed in appendix S. Out of the 31 design recommendations only 42% were adopted in the prototype head injury survey application.

6.4 Qualitative themes

Patients and staff cognitive walkthrough were audio recorded and transcribed verbatim. Eight transcripts underwent a thematic analysis using Braun and Clarke's (2006) six phase qualitative analytic model. The semantic themes for this research are presented. A full narrative of patient and staff usability experiences of the head injury survey application is provided and evidenced with data extracts. This section outlines three themes and these are illustrated in figure 4.

Figure 4- Thematic map



To ensure participant data was completely anonymised participant codes were generated and a key is provided in table 7.

Table 7- Participant description codes

Code	Description
PFPC	Patient female personal computer
PFTC	Patient female tablet computer
PMPC	Patient male personal computer
PMTC	Patient male tablet computer
SFPC	Staff female personal computer
SFTC	Staff female tablet computer
SMPC	Staff male personal computer
SMTC	Staff male tablet computer

6.5 Theme one: User interface problems and improvements

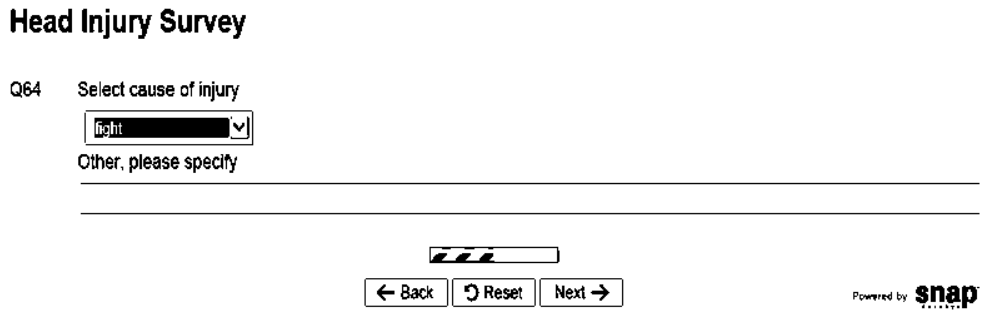
6.5.1 Navigation

Patients and staff disliked how survey questions were ordered when eliciting data relating to lifetime exposure to TBI. The systematic process of identifying all head injuries combined with repetitive questioning about these injuries made the experience tedious and boring for patients. Staff found the memory recall strategy of recording the most recent head traumas and working backwards through time unusual.

> 'It felt strange going backwards. I.e. going into the last injury. First. And then going to a childhood injury at the end' (SMPC Line 337)

For two of the patients a usability problem occurred when they were provided with a list of injury descriptions. They took this as an opportunity to select every head injury event they had experienced within the set time frame (See figure 5).

Figure 5 - Injury description



They assumed all further questions related to every head injury identified and not individual head trauma events.

> 'Cos that means I'll have to go through all of them [head injuries]. Maybe I dint understand that' (PFPC Line 256)

One staff member suggested all the head injuries throughout lifetime should be recorded first before asking specific details about each injury, starting with the oldest injury and working forwards through time. The procedure of recording every head injury before asking specific questions more closely reflects the OSU TBI-ID semi structured interview administration method.

The nature of the injuries and the life context of the patient group made the recall of head trauma problematic (see section 6.5.3 Context). Impaired working memory presented several challenges in terms of recollecting the number of head injuries, the age at which the injury occurred, severity of the injury and the type and level of medical care received. The navigation process of systematically going through each injury increased working memory load and patients were unable to recollect what injuries they had initially identified when answering later questions. This usability problem was further compounded by the fact all patients experienced multiple head injuries throughout their lifetime and did not want to systematically go through each head injury. They disliked the sequential structure of the survey, finding the questioning repetitive and tedious, making it difficult to concentrate on some of the

questions being asked. The depth of questioning for each head injury was found to be too time consuming and slow. Completion of the survey needs to be more rapid and capable of holding the patient's attention through displaying key information immediately in the line of sight with an eye-catching presentation.

> 'I find it really hard to remember the incident in detail' (PMTC Line 246)
>
> 'I can't remember what I've done at beginning of it [Head Injury Survey]. That's how much I forget things so quick.' (PFPC Line 262)
>
> 'I've had multiple head injuries, so. I don't want to be going through every one' (PFPC Line 243)

6.5.2 Data entry and technology

Patients and staff mostly had different usability perspectives for data entry and technology. Staff were critical of a measure which collected retrospective head injury data. They thought the instrument would be subject to false positive responses and recall bias. One staff member considered some of the survey questions to be too leading, potentially resulting in false positive outcomes. The nature of the injuries and the amount of time which has passed since the head injury occurred was thought to cause recall bias, especially if they were injured during childhood. One staff member questioned how a patient could estimate duration of loss of consciousness given the nature of the injury.

> 'It's almost like prompting. So you're eliciting information first. Which could then trigger a false response.' (SMTC Line 357)
>
> 'Less than five minutes. I'd probably want to ask how you know that.' (SFPC Line 47).

Patients' usability concerns were more practical as they struggled with basic mouse and keyboard operation and following onscreen instructions. Two patients needed help with the use of a space bar and delete function. One patient did not know how to operate the virtual keyboard and would have preferred the addition of predictive text found in mobile devices.

> 'Where's the space' (PFPC Line 23)
>
> 'How do I cross that out?' (PMPC Line 25)

> ‘It usually says it on top, dunt it. Yea. When you’re trying to, write it. An it ‘ant come up’ (PFTC Line 27, 28)

Personal computers appeared to cause greater feelings of frustration in comparison to the tablet computers. Limited IT skills made data entry a stressful experience. Both patients who used personal computers wanted to minimise the amount of interactions they had with the survey. They found having to select the ‘next’ button to change screens particularly irritating. The touchscreen user interface was favoured as there appeared to be greater familiarity with the technology.

> ‘I just don’t know how to do it on computer... It’s ‘cos I’ve never used ‘em before’ (PMPC Line 21)
>
> ‘I don’t how to use this, you’ll have to show me how to do it. I’ll get irritated’ (PFPC Line 24)

The staff who used tablet computers were in favour of the design concept, overall opinion was the head injury survey application would be a helpful and useful tool. The portability of the technology was highlighted as being the most significant development as it would lead to increased opportunities to screen for head injury with the immediacy of being able to use your phone.

> ‘The fact that it’s on portable… equipment is really useful ‘cos I think people will do it a lot more. Rather than having to find a computer’ (SFTC Line 394)

The tablet computers were not without limitations as an unresponsive touchscreen combined with slow screen changes made completing the survey frustrating for patients and staff (See section 6.7.2 managing rapport). A weak Wi-Fi signal made connecting to the remote server problematic when interacting with Snap Mobile Anywhere (Snap Surveys Ltd, 2016).

> ‘Pressing it again, it doesn’t seem to be doing anything.’ (SFTC Line 22)
>
> ‘Still very slow’ (SMTC Line 18)

Entering incorrect data frequently occurred as patients misinterpreted onscreen instructions. Three of the four patients were unfamiliar with how to complete open field boxes. The instruction 'click here' was meaningless to both patients using the personal computer. In future user interface iterations patients requested the inclusion of screen readers, voice recognition and drop down menus instead of open field boxes.

> 'Select cause of injury. Click here. I don't know how to do that' (PMPC Line 107)
>
> 'Drop down numbers. Yea, so you can tick 'em off' (PFTC Line 106)
>
> 'If it's gonna be a survey on a computer it needs to be talking to you, it needs to be asking you questions' (PFPC Line 413)

The two female patients preferred to explain to a staff member what head injuries they had experienced rather than self-completing the survey questions, especially if they were associated with personal life events. The staff member would need to be familiar but not someone they work with on a regular basis as they were worried how the disclosure of domestic violence would impact on the staff member.

> 'You know like a survey like this, I think it's easier to sit down with somebody, an explain what's happened to you.' (PFPC Line 377)

6.5.3 Content

Patients and staff had similar usability concerns about the amount of on screen text. All patients were overwhelmed by the extent of text contained within screens (see figure 6).

Figure 6 - Head injury risk markers

Head Injury Survey

If any of these symptoms occur after a head injury this can be a sign of a more severe injury

Q79 Immediately after the fight injury did you have any of the symptoms below?

- [ ] clear fluid running from the ears or nose
- [ ] black eye without receiving any damage to the eye
- [ ] bleeding from one or both ears
- [ ] new deafness in one or both ears
- [ ] bruising behind one or both ears

Why are we asking you this question?
If any of these symptoms occur after a head injury this can be a sign of a more severe injury.
If you have clear fluid coming from your nose after a head injury it could mean you have a fracture of your skull which needs urgent medical assessment. Clear fluid does not include tears caused by crying or from a runny nose if you have a cold or hay fever. Bleeding disorders are conditions where there is a problem with the blood clotting process in the body.
You can select more than one symptom, e.g. clear fluid running from the ears or nose AND bleeding from one or both ears.

Please select next if none of the above.

← Back | Reset | Next →

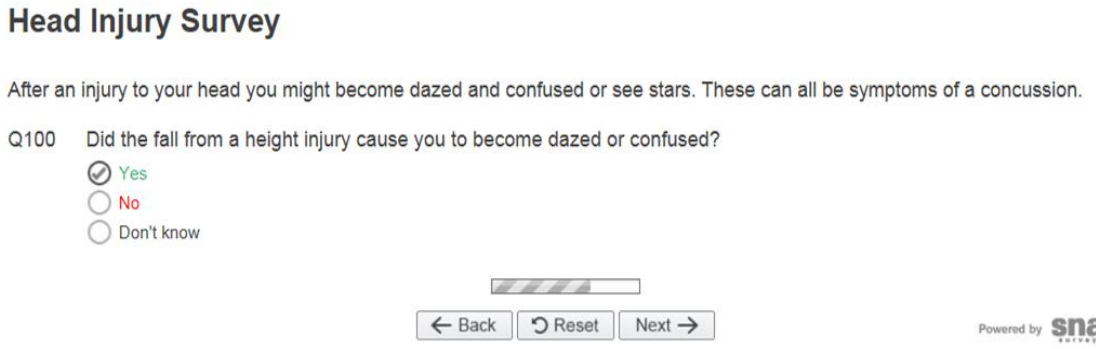
Powered by snap

To cope with the amount of text two patients resorted to skim reading. Future design iterations will require minimal content in terms of screen instructions and survey questions. Long sentences combined with words containing multiple syllables further reduced the readability of survey questions and on screen instructions for patients.

> ‘Just scan read the top bit.’ (PMTC line 222)
>
> ‘Too much to take in.’ (PFTC line 214)
>
> ‘Don’t understand what that’s just said.’ (PFPC line 115, 116)

Staff considered grammatical errors, unclear instructions and sentences which did not flow well to be usability barriers to building and maintaining rapport with patients. Staff wanted identified injury descriptions to be embedded in future survey questions. Snap Mobile Anywhere (Snap Surveys Ltd, 2016) offered the feature of including injury descriptions in later survey questions. Unfortunately this software feature caused a reduction in readability, making some of the sentence structure grammatically incorrect (see figure 7).

Figure 7- Dazed, disorientation and confusion



'That… feels weird saying fall from a height injury.' (SFTC line 215)

Future design iterations will require a more dynamic application program interface which is more grammatically sensitive to the inclusion of injury descriptions.

A consistent usability problem was experienced by both patients and staff when they did not see the change in wording between two screens for 'head injury problems and symptoms'. The first screen identified problems and symptoms immediately after the head injury and the second screen identified problems and symptoms which had remained. This was evidenced when the screen changed to remaining problems and symptoms by either surprise at the lack of available options or the belief there was a duplication of items they had selected on the previous screen. To help patients and staff differentiate problems and symptoms associated with head injury from other causal factors, the words 'than normally' (SFPC Line 179) could be added to identify whether the head injury had changed their cognitive, emotional, behavioural or physiological functioning.

> 'That's a repeat 'cos you asked about balance problems in the previous question. I dunno. Feels, feels like there might have been duplication.' (SMPC Line 171, 172)
>
> 'I didn't read that. Hang on a minute, awww, for god's sake, I'm going to un-tick all of those 'cos I've just realised it said immediately after the injury.' (PMTC Line 219)

Patients favoured simplicity over comprehensive questioning. They found the Head Injury Survey to be repetitive and they requested a more straightforward.

> 'Could be simplified. For me.' (PFTC Line 304)
>
> 'Asking me too many things.' (PMPC Line 584)
>
> 'I'm having to go through same thing over and over again.' (PFPC Line 266, 267)

Survey questions need to be intuitive and the area of the survey which identifies clinical markers associated with mild TBI was considered to be a good example (see figures 8 - 10).

Figure 8- Post traumatic amnesia screen

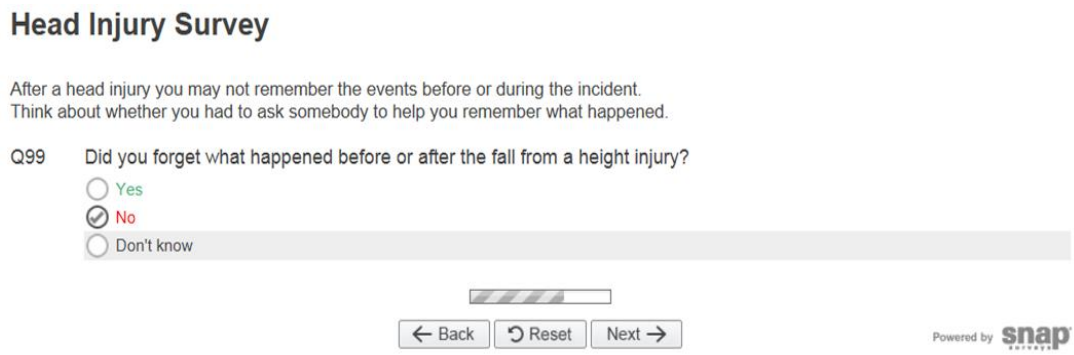
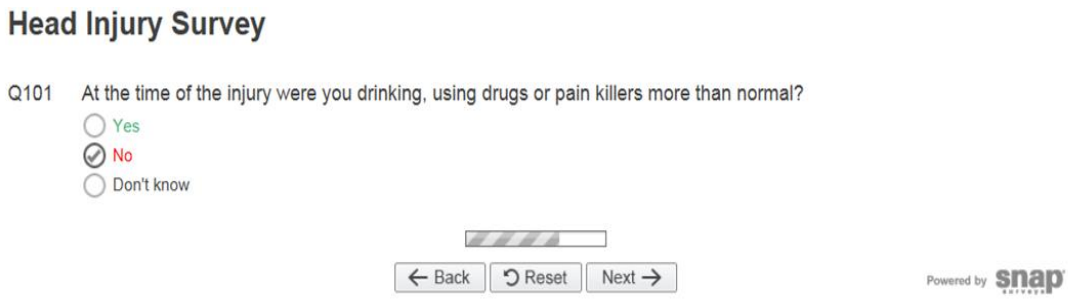


Figure 9- Dazed, disorientation and confusion screen

Figure 10- Mild TBI marker screen



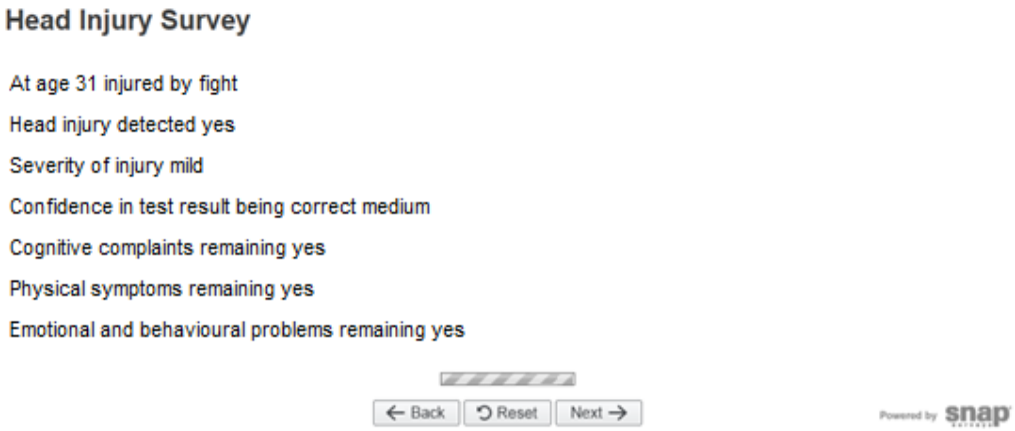
> ‘I like how this has become intuitive to my natural brain thoughts or is it the other way round.’ (PMTC Line 249)

Interpreting the survey findings created several usability issues for patients and staff. Patients considered the findings on the results screen to be information for staff.

> ‘So this is more for you guys really isn’t it, I don’t know what I’m supposed to be doing here.’ (PMTC Line 333)

The way test results are conveyed requires further development to ensure the findings are meaningful to patients and staff. Three out of the eight outcome variables created confusion for staff. Age, severity of injury and confidence in test result have the greatest redesign priority (see figure 11).

Figure 11- Survey results screen



There was a misunderstanding of the variable ‘age at time of injury’ as it was believed the finding was calculated by number of years that had passed since the injury event, instead of how old the patient was when injured. One staff member thought ‘severity of head injury’ was determined by extent of medical intervention rather than the detection of loss of consciousness (LOC), post traumatic amnesia (PTA) or dazed, disorientation and confusion (DDC). Providing the variable ‘confidence in test result’ for each head injury detected created uncertainty when the variable outcome, e.g. low, medium or high, changed for individual injuries.

‘The age is based on how long ago the injury was I’m guessing.’ (SFPC Line 442)

‘Severity of head injury mild. Erm… I mean that’s based on… the fact that he didn’t get medical treatment it doesn’t mean to say it was a mild injury.’ (SFPC Line 461)

‘Confidence in test result being correct, medium. What, what does that mean?’ (SMTC Line 461)

Two omissions in content were identified; test results introduction screen and referral options to specialist services if TBI was detected. The inclusion of a test result introductory screen could mitigate some of the confusion as there was uncertainty as to how the instrument detected TBI.

‘There’s no sort of introduction to it. You just go from asking some questions into a summary.’ (SFTC Line 330)

‘What I could do to sort the problems.’ (PFTC line 389)

6.5.4 Page Layout

Staff had minimal concerns about the page layout. In contrast, patients found inconsistent page layout, choice of button colour and font size to be obstacles to usability.

‘The text is up and then down and all over the place.’ (PMTC line 270)

Choice of colour for buttons was confusing and was open to misinterpretation. One patient interpreted the colours green/red on the yes/no buttons as either positive or negative responses to the question. Colour choice could have unintended ramifications for patients with low reading ability who may rely upon similar interpretations when making decisions about choice selection.

‘Press ‘yes’ cos’ it’s green and that’s good.’ (PMTC line 45)

Two patients found the font size to be too small and one patient was not able to read the text.

‘It’s too small.’ (PFTC line 44)

‘It really does need to be a bit bigger.’ (PFPC line 113)

Minimal on screen information was preferred with a consistent layout. Inspiration was taken from a bingo card, preferring a more grid-like formation.

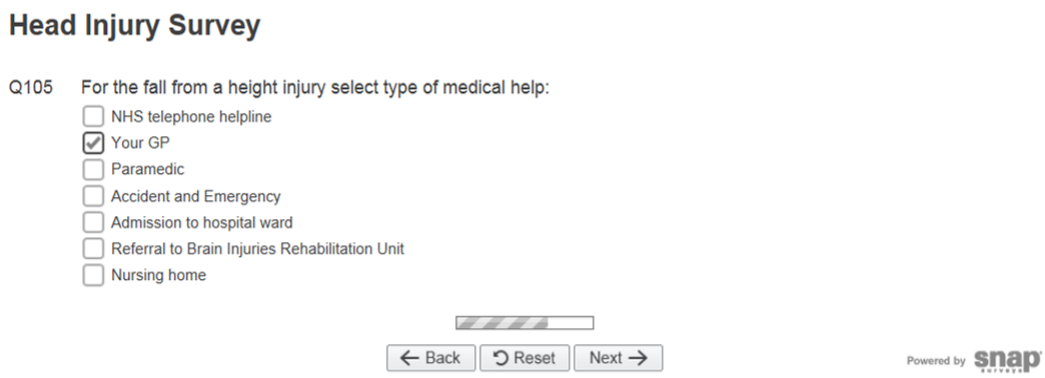
6.5.5 Terminology

Staff were concerned there were multiple terms being used for loss of consciousness with 'knocked out' being preferred. Some of the language was described as too clinical and stigmatising in places and may not be understood by some of the patients, e.g. fatigue, cognitive complaints, assaulted, consciousness, unconsciousness and behaviour problems.

> 'There's 3 different terms there. For the unconsciousness. 'Cos there's the, er, knocked out. Blacked out. And unconscious.' (SMPC Line 57)
>
> 'A lot of my clients maybe wouldn't know what cognitive complaints were.' (SFTC Line 357)

Terminology impacted on patients in two ways. The language used did not reflect the patient's circumstances or some of the words had too many syllables and made reading difficult. For one patient who had served in the armed forces, the terminology used to describe the medical care he received did not represent his experience when serving on a military base (see figure 12).

Figure 12- Types of medical help screen



> 'The thought of ringing an NHS line from Afghanistan makes me laugh' (PMTC Line 108)

Low reading ability was probably the most significant usability barrier for patients and made navigating on screen information difficult. Sentences were scan read, skimming over words which were not understood, leading to the content being repeatedly read if it did not make sense to the patient. The comprehension of a sentence was not achieved until all the content had been read and misunderstood words would then be placed in context. Survey language needed to be pitched at a pre-literate level following easy read principles undergoing comprehensive analysis using the Flesch-Kincaid Grade Level Readability Formula (Kincaid et al., 1975).

> 'I'll just carry on reading it, then when I get to the end sometimes it makes sense' (PMPC Line 262)
>
> 'when I look at a word sometimes I see it an, an I say it. But I say it wrong' (PMPC Line 260)

Low reading ability made some of the terminology inaccessible and the table (Table 8) below illustrates some of the most problematic words.

Table 8- Problematic terminology

Terminology	**Extracts**
Pain	"using drugs or… Pills? Is that P… P, A. I, N." (PMPC Line 231)
Consciousness	"did I lose con, like conscience. I can't say it." (PMPC Line 337)
Admitted to accident and emergency	"that word there." (PMPC Line 399)
Brain injuries rehabilitation unit	"That." (PMPC Line 404)
Next to continue	"it was… next to kin. Er, that's who I had to get in touch with." (PMPC Line 418)
Irritable	"I can't say the word" (PMPC Line 569)

6.6 Theme Two: Living with TBI

Limited IT skills, low reading ability and suspected neurodisability not only made completing the survey problematic but had implications for patients' daily lives. Gaining a better understanding of what it means to live with TBI will serve to inform

the head injury survey application's development and enhance usability. Design iterations will need to be more sensitive to:

- Trauma
- Coping strategies
- Context

6.6.1 Trauma

The implication of screening for past traumatic life events needed careful consideration with respect to the emotional impact of completing the survey. A retrospective measure which encouraged the recollection of past traumas was upsetting Emphasising the need for follow up support, which was anticipated when seeking ethical approval for the study. Prior to completing the head injury survey, patients had not associated some of the problems and symptoms they experienced with head injury. The frequency of completing the survey should be restricted as the experience of recalling traumatic injuries was distressing for some patients, especially if they had been subjected to domestic violence. The survey needed to be sensitive to the disclosure of domestic violence as it was not viewed as being comparable to other injury types like motor vehicle accident. Domestic violence was a prevalent cause of injury for female patients. The nature of the injury was often degrading and distressing for the patient to recall. Violence was a risk factor across genders. Procuring illicit substances could sometimes result in violent incidents in which head injuries were sustained. For patients who had a background in the armed forces there could be a reluctance to disclose the full impact of their past head injuries, as perceived vulnerability amongst the higher ranks was deemed to be unacceptable.

> 'Most women, if they have had head injuries a lot of them have come from domestic violence' (PFPC Line 293)
>
> 'I only know I lost consciousness though. Because, he took a photo of me. An put it on me phone and left it for me to see' (PFPC Line 306)
>
> 'I was going up trying to get drugs, from Chapeltown, and er. I ended up getting in a fight, with some black lads, er. And, one of 'em hit me, over the head, er. And broke a load of, like… chairs' (PMPC Line 409)

> ‘I know that sergeants and above would be very kind of wanting to seem a bit more rugged and less likely to be taken down by something like a head injury’ (PMTC Line 302)

6.6.2 Coping strategies

Many patients relied considerably on their family and friends to help them cope with the effects of their neurodisability. Patients used several coping strategies in an effort to manage impaired judgement and emotion regulation. Drug use and family support were typical methods of coping. Having impaired working memory generated feelings of anxiety as they lived with the knowledge they could not recall things they had done on a day-to-day basis. Cognitive complaints made learning new skills challenging and undertaking mundane tasks frustrating if they could not recall the purpose of the activity they set out to do. This dependency on others extended to decision making when determining whether medical help was required. The severity of most head injuries led to neuroimaging. The patients were generally reluctant to seek medical help following a head injury. Self-assessment of severity of injury was typical even when they had sustained bruising to the head following assault with a baseball bat. There was frequently a delay between sustaining a head injury and the provision of medical help. Encouragement mostly came from family members or emergency response professionals to seek medical help. The police tended to be the first responders to head injury incidents and often accompanied the patient to hospital. Staff thought the head injury survey application instruction to ask friends or relatives for support was helpful when determining whether there had been any changes in the patient’s mood or behaviour following a head injury. A combination of simple on screen instructions and support from family and friends could help the patient clarify whether they were affected by some of the problems and symptoms described in the survey.

> ‘I always ask her [girlfriend], you know if I ever forget things and that. Er, or what days I’ve got to go places.’ (PMPC Line 176)
>
> ‘I get in mood swings. Er… When, when, er… Like, er… Me girlfriend seems to be able to cool me down, by talking to me.’ (PMPC Line 572)

> ‘When I had me head injury, er, it were right down to me skull. Er, it were the policeman that said to me, er. I won’t ask you anything or do anything if you go straight to the hospital, ‘cos I can see your skull.’ (PMPC Line 406)

6.6.3 Context

The psychoactive effects of some of the illicit substances used were detrimental to working memory and caused transitory or permanent impairment. Patients had an awareness their memory was impaired and the knowledge there was a time in their lives when remembering things came easier to them. It was difficult for the patients to differentiate whether the cognitive, emotional, behavioural and physiological symptoms described were associated with head injury or other factors like lifestyle and mental health. The regimented lifestyle of serving in the armed forces had the effect of minimising any potential deficits in working memory. Levels of concentration are influenced by your environment and the change in experience can be quite extreme when making the transition from a military base in a hostile setting to civilian life. Changes in behaviour were more likely to be interpreted by family and friends as being attributed to the experiences of serving in the armed forces on an operational base and not necessarily connected to any head injuries sustained.

> ‘I’m totally more forgetful and sometimes I do really struggle with concentrating’ (PMTC Line 159)
>
> ‘I use, er… diazepam. An I sh, and I shunt use ‘em. And that makes me forget things.’ (PMPC Line 233)
>
> ‘Friends and relatives are unlikely to have said oh he came back from Afghan, he got hit in the head and that’s what’s changed his behaviour. They’re more likely to think it’s potentially the experience out there’ (PMTC Line 155

6.7 Theme Three: High tech or low tech healthcare

For front line staff working with an at risk patient group for TBI, two themes became apparent in the administration of the instrument:

- To screen or not to screen
- Managing rapport

6.7.1 To screen or not to screen

The use of screening instruments needed careful consideration, requiring clinical judgement as to when it was appropriate to implement a potentially distressing intervention. The purpose of the head injury survey application was not clear for staff beyond gathering a history of head injuries. For the staff members, understanding the benefit of screening needed to clearly outweigh any harms which could occur. Knowing exactly when and where to refer on to more specialist services was crucial, emphasising the importance of ensuring there was a useful outcome for the patient if you chose to screen for a potential health related problem. Some of the content within the information sections was thought to be potentially distressing for patients. They opted to omit certain information which was available to them on the screen as they thought it might upset the patient.

> 'Could be quite scary, especially if the incident was 2 years ago. An they start panicking as to, the fact they haven't had medical, urgent medical… assistance.' (SFPC Line 127)

6.7.2 Managing rapport

The ability to maintain good rapport with their patients was of particular importance to staff. They identified two areas in which the head injury survey application inhibited rapport; too much onscreen information and slow screen changes. It was thought having too much screen content would restrict building rapport with the patient, combined with slow screen changes interrupting the flow of the survey resulting in the staff member feeling uncomfortable and causing frustration. The tablet computer's touch screen technology lacked sensitivity, making data entry difficult and item selection problematic. All staff had a good understanding of the needs of patients with suspected neurodisabilities, namely limited attention spans and becoming overwhelmed by too much information.

> 'If this was a client I'd be feeling a bit awkward now at the time it's taking to move between the screens.' (SFTC Line 27)
>
> 'You need to be careful of the sensitivity of the touch screen' (SFTC Line 388)

> ‘It’s that risk of bombarding people isn’t it, with, with too much information. Erm. Especially somebody with a brain injury who might have a very short attention span.’ (SMTC Line 206)

The pace of the survey was inhibited as the screen instructions were on a different page to the survey questions. The instructions should be located above the survey question on the same page. When there was an expectation for staff to relay information to the patient, a heading should have been provided identifying the content as information. Combined on screen information with survey questions created confusion as staff were unable to differentiate between screen instructions and the key survey question. It was seen as their responsibility to filter out and refine the information they provided to the patient. Judgement was exercised when evaluating what information they fed back to the patient and omitted what was deemed to be irrelevant. Acknowledging until they were familiar with the survey they were more likely to have greater fidelity to the questions. This meant they would read the screen content verbatim so the wording needed to flow more easily as gaining familiarity with how the questions were phrased is unlikely if head injury screening is not routine practice. Several grammatical and syntax errors were identified, e.g. become irritable, binge drunk, dazed and confusion. The use of prompts was requested so staff did not have to read all screen instructions verbatim.

> ‘I… keep wanting to add words in to make it… read. A bit more easily.’ (SFTC Line 193)
>
> ‘As a practitioner am I supposed to be reading everything out to the, to the patient? Or is that more for my information.’ (SMTC Line 155)
>
> ‘Some of it would be to prompt… how you could word it, or what you could say.’ (SFTC Line 383)

6.8 Quantitative - problem discovery

This section presents the problem discovery results (Tullis and Albert, 2013). Categorical data is summarised using frequencies and proportions. Graphical summaries such as bar and pie charts have been used to display ordinal data types. Frequency and severity are ranked using four point likert scales developed by Rubin (2011). Frequency is determined by the identification of unique usability problems

across five predefined categories; terminology, navigation, content, page layout, data entry and technology. The identified unique usability problems in the five predefined usability categories received individual severity rating scores and a mean was calculated for each category and a severity rating score assigned. Usability criticality score was achieved by combining frequency and severity rating scores and has a range of between two and eight, the higher the score the greater the redesign priority (Rubin, 1996, Rubin and Chisnell, 2011). Issue based metrics catalogue the frequency, severity and criticality scores for patients and staff for the five predefined categories (Tullis and Albert, 2013) and can be viewed in tables 9 and 10.

Table 9- Staff problem frequency count

Categories	Frequency Count	%	Frequency Rank	Severity Mean	Severity Rank	Criticality Score
Data Entry and technology	5	29%	2	1.6	2	4
Terminology	3	18%	2	1.6	2	4
Navigation	2	12%	2	1.5	2	4
Content	6	35%	2	1.3	1	3
Page Layout	1	6%	1	2	2	3

Table 10 - Patient problem frequency count

Categories	Frequency Count	%	Frequency Rank	Severity Mean	Severity Rank	Criticality Score
Navigation	3	19%	2	3.7	4	6
Data Entry and Technology	5	31%	2	3	3	5
Content	3	19%	2	3	3	5
Page Layout	3	19%	2	2.3	2	4
Terminology	2	13%	2	2	2	4

There were some major usability problems as only 1 in 4 patients could complete the head injury survey independently. The category with the highest criticality score (CS = 6) was navigation, this consisted of 19% of unique usability problems. Navigation

achieved the highest severity rank (S = 4) and presents the greatest challenges for redesign. Page layout and terminology had the lowest redesign priorities for patients as they both had criticality scores of four, however, they differed in unique usability problem count. Data entry and technology had the largest proportion of usability problems at 31% presenting a severe limitation to usability (S = 3) as five unique challenges were identified:

- Completing open field boxes
- Interpreting on screen instruction
- Slow screen changes
- Unresponsive touch screen
- Keyboard and mouse operation

Content had three unique usability problems (19%) and was equally limiting for patients in comparison to data entry and technology (S = 3). All four staff were able to complete the head injury survey independently. Data entry and technology, terminology and navigation had equal criticality scores (CS=4). Content had the highest unique frequency count at 35% and the lowest severity rank (s=1). Page Layout has the same criticality score as content (CS=3). Page layout has the lowest frequency count at 6% and equal severity ranking (s=2) with navigation, terminology and data entry and technology. Four out of the five predefined categories had moderate severity usability issues.

6.9 Conclusion

This chapter presented the findings from the formative usability evaluation. Patients and staff tested the prototype user interface for the head injury survey application. They offered unique usability perspectives for the five pre-defined user interface categories, identifying both problems and solutions with the initial instrument design. The cognitive accessibility of the user interface was better understood by specifically recruiting patients with suspected neurological disability. Patient's experience of living with TBI revealed important usability insights. The disclosure of traumatic events and the reliance upon family and substance use to cope with neurological deficits will shape the next user interface design. Developing a prototype which is more sensitive to

low reading ability, limited IT knowledge and neurological disability will be the greatest design priority.

Staff's usability concerns offered insight into the importance of managing rapport and minimising the emotional impact of a potentially distressing intervention. Through combining patient and staff design recommendations, the next iteration will be more straightforward with minimal on-screen content. All key information will be displayed on screen. Relevant prompts will accompany survey questions to guide staff in the administration of the instrument. Greater transparency will be provided in how the head injury survey application detects TBI with the addition of referral guidance to specialist brain injury services. A quantitative problem discovery revealed the most critical areas for user interface redesign and will serve as a useful guide to the prototype's development life cycle.

7.0 Discussion

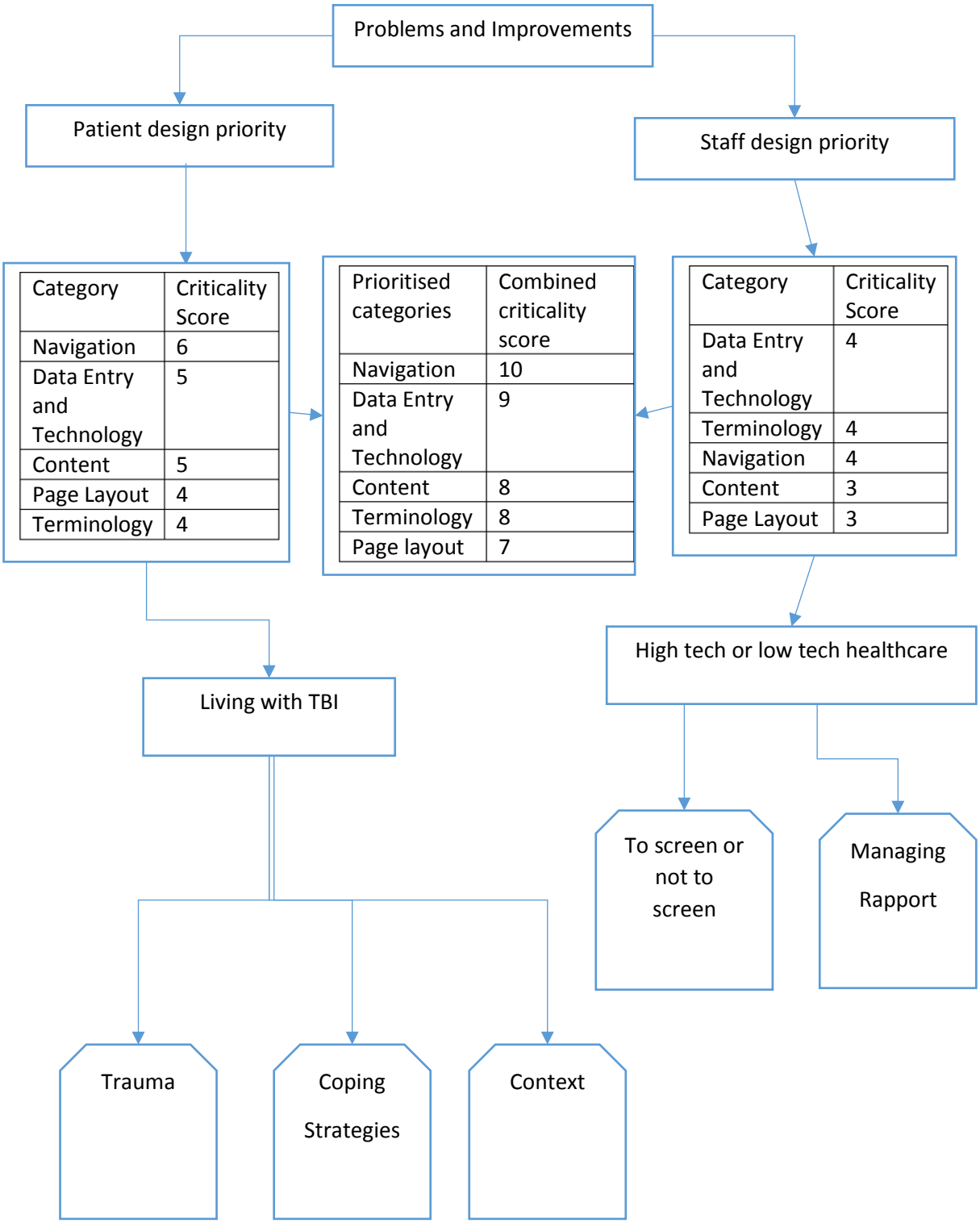
7.1 Introduction

This chapter offers a discussion of the human centred design and evaluation findings. The mixed methods data will be integrated and interpreted in the context of wider usability literature. A description of the main formative usability findings are outlined identifying user interface redesign priorities. Implications for traumatic brain injury (TBI) screening are discussed in the context of community drug and acohol treatment. Strengths and limitations of this formative usability study will be presented. The chapter will conclude with considerations for policy, practice and future research.

7.2 Description of mixed methods formative usability findings for patients and staff

Patients and staff had different redesign priorities for the head injury survey application's user interface. The theme user interface problems and improvements had five predefined categories which underwent problem discovery analysis using basic descriptive statistics (see Section 5.9 Quantitative – descriptive statistics). A criticality score was determined by combining the frequency and severity of identified usability problems. Rich problem descriptions were offered for each of the predefined categories. Patients had one usability theme; living with TBI and staff had one theme; high tech or low tech healthcare. The thematic analysis findings and usability problem discovery data for patients and staff in community drug and alcohol treatment are illustrated in figure 13.

Figure 13 -Integrated formative usability evaluation findings



Category	Criticality Score
Navigation	6
Data Entry and Technology	5
Content	5
Page Layout	4
Terminology	4

Prioritised categories	Combined criticality score
Navigation	10
Data Entry and Technology	9
Content	8
Terminology	8
Page layout	7

Category	Criticality Score
Data Entry and Technology	4
Terminology	4
Navigation	4
Content	3
Page Layout	3

7.3 User interface redesign priorities

This section integrates the mixed methods findings from the formative usability evaluation of the prototype head injury survey application user interface. Patient and staff priorities for user interface redesign are outlined. Patient and staff criticality scores from the problem discovery analysis were combined to generate a priority list with the five predefined user interface categories.

7.3.1 Priority one: Navigation

For patients, navigation made the head injury survey application unusable and three unique usability problems were discovered. Overall, navigation was not sensitive to the needs of patients with neurological deficits. Future user interface design iterations need to ensure task performance is not dependent on memory recall as patients found navigating multiple screens increased working memory load. Minimising user interface navigation and ensuring key elements of the system are available on screen at all times has been found to reduce working memory load (Cole and Dehdashti, 1990, Inglis et al., 2002).

Negotiating repetitive systematic questioning about lifetime exposure to TBI fatigued three out of the four patients and they could not complete the head injury survey. Length of the survey was an important consideration and a balance must be found between ensuring a comprehensive TBI screening has been conducted whilst avoiding patient fatigue. Reduced administration time has been found to be a fundamental component to the adoption of health informatics technology (Gagnon et al., 2012). A user interface is required which uses repetition in a limited way without inducing frustration.

7.3.2 Priority two: Data entry and technology

Data entry and technology required moderate effort by staff to negotiate and five unique usability problems were identified. Staff usability concerns from a data entry perspective were orientated towards how the decision support software made clinical judgements when detecting TBI. Staff questioned the validity of the retrospective measure. They wanted transparency in how the decision support software processed

clinical data. This was a relevant concern as the head injury survey application has not yet undergone empirical validation. Healthcare professionals are more likely to invest in clinical decision support software which can demonstrate how it is robust, safe and facilitate delivery of care (NHS Innovations South East, 2014).

Staff thought the portability of the technology would enhance patient benefit through increased access to a TBI screening instrument. This finding resonates with NHS guidelines on mobile application development when considering hardware. Mobile technology offers greater portability and could be a helpful tool in outpatient clinics (NHS Innovations South East, 2014). Mobile hardware is not dependent upon patient location and provides the benefit of enhanced clinical decision making, an important feature for staff working in a community drug and alcohol team who do not have the opportunity to access a networked computer or paper based resources (NHS Innovations South East, 2014).

Three out of four patients information technology skills severely limited their capacity to enter data and use computer based hardware (Wehmeyer et al., 2004). Patients were unfamiliar with user interface features like open field boxes and information technology language. Mouse and keyboard operation required basic instruction from the test administrator. Lányi et al. (2012) designed user interfaces for students with intellectual disability and generated several design recommendations which could be applied to future design iterations. For example, the user interface should make use of accessibility features allowing multiple user groups with specific needs the ability to customise the user interface to their own individual preferences (Lányi et al., 2012). The patient stakeholder expert reference group requested a customisable user interface, a design feature which will need to be incorporated into the next iteration. Patients made specific requests for the head injury survey to make use of both screen reading and voice recognition software.The W3C Web Accessibility Initiative provides technical guidelines for designers and software developers in how to ensure their applications meet the needs of users with auditory, cognitive, neurological, physical, speech, and visual disabilities (W3C, 2017).

7.3.3 Priority three: Content

Three unique usability problems were identified with user interface content which severely limited patient's use of the Head Injury Survey Application. Low reading ability introduces obstacles to user-interface interaction. Most health applications require a high level of reading ability to negotiate. Instructions are frequently delivered in complex formats which could be beyond the reading ability of some of the patients receiving community drug and alcohol treatment with co-occurring TBI and substance use disorder (American Psychiatric Association, 2013). Universal graphical interfaces are increasingly being used, however, text remains the predominant form of communication. Sounds can be used to prompt although it is frequently difficult to interpret their meaning, even for competent IT users (Lányi et al., 2012). Tones accompany text messages with the assumption the user has the capacity to read the instruction which restricts patients with complex needs access to the user interface. Patients found the head injury survey in this study relied too heavily upon text based instruction. Future design iterations need to be subjected to The Flesch-Kincaid Grade Level Readability Formula (Kincaid et al., 1975) to ensure the use of plain English and minimal onscreen text.

Staff correctly anticipated the volume of onscreen text would overwhelm patients. Their usability concerns were focused on how they would administer the instrument and maintain rapport with their patients. Staff requested the use of prompts so they did not have to read on screen text verbatim. Staff values in this usability study wanted to avoid a "one size fits all" approach. Prompts would lend staff the flexibility to meet the unique needs of patients, giving them permission to make further enquiry to obtain the most useful information.

The survey results summary screen consistently caused confusion to both patients and staff. The eight outcome variables need to be conveyed in a manner which supports improved comprehension as informing a patient they potentially have a brain injury following a head trauma event could be very distressing. Patients and staff both requested the inclusion of referral guidance to specialist brain injury services. This would be a significant design consideration and was initially anticipated by an addiction specialist doctor in the stakeholder expert reference group meetings.

Integrating referral decision support was beyond the functional capability of Snap Mobile Anywhere (Snap Surveys Ltd, 2016).

7.3.4 Priority four: Terminology

Staff found three unique usability problems with the terminology used. They considered some of the language to be inconsistent and potentially distressing for patients. They wanted language to be plain English, non-clinical, and any stigmatising terms be removed. For patients, language needed to reflect their lived experience of sustaining head trauma. Terminology used in health applications is frequently complex and for patients with limited information technology skills could introduce unfamiliar computer based language. Language associated barriers are typically identified through considering the terms used in most applications. Patients with TBI and low reading ability tend to understand language in a literal, concrete way and abstract metaphors should be avoided (Wehmeyer et al., 2004). Instead unique and descriptive text should be used as patients in this study were unfamiliar with the term 'click here' for hyperlinks (Lányi et al., 2012). Patients who receive community drug and alcohol treatment who have limited information technology skills may avoid computer based hardware if they anticipate the experience will be frustrating.

7.3.5 Priority five: Page layout

Patients found three unique usability problems with page layout requiring moderate effort to negotiate. An inconsistent page layout and colour choice for on screen buttons further reduced readability and task comprehension. The potential for misunderstanding on screen tasks is high if interpretation is derived from colour alone by patients with low reading ability (Lányi et al., 2012). This occurred for one patient who specified he had diagnosed dyslexia when he interpreted the green/red on the yes/no buttons as a positive or negative response to a question. For patients with below average reading and writing ability solutions to a predominantly text based user interface are required. Graphics, animation and sound could be used as potential design solutions (Lányi et al., 2012). Patients preferred a user interface with minimal on screen text, large fonts with consistent page layout in a grid formation and eye catching presentation. Standardised page layouts can better support patients with

limited attention spans and impaired working memory (Wehmeyer et al., 2004). Staff wanted a user interface which had improved labelling to better differentiate between on screen instructions and survey questions.

7.3.6 User interface redesign summary

Patients and staff identified many of the same usability challenges with the user interface. The rich problem descriptions for the two user groups originated from unique usability perspectives. The solutions to how the identified problems could be resolved had the potential to benefit both patients and staff. These findings are in keeping with emerging evidence which suggests designing for a wide range of end users with diverse needs can lead to superior design (Shneiderman, 2000).

7.4 TBI screening in community drug and alcohol services

This section provides guidance to staff in community drug and alcohol teams (CDAT) in how to conduct TBI screening. Clinical markers for identifying patients at risk of TBI will be provided and direction in how to administer a TBI case finder will be discussed. Finally the implications for integrating mobile health application technology with existing information technology infrastructure will be explored and how these insights could shape the user interface design for the head injury survey.

7.4.1 Mental Health

Epidemiological TBI studies offer insight into potential clinical markers for patients at risk. Patients with head trauma are 2.8 times more likely to develop a mental health disorder compared to non-TBI patients (Fann et al., 2005). A prospective cohort study by Bryant et al. (2010) followed 817 head trauma patients over a 12 month period, 23% of patients developed a mental health disorder which was not present pre-injury. Depression (9%) and generalised anxiety (9%) were the most prevalent disorders (Bryant et al., 2010). Staff in community drug and alcohol teams routinely screen for depression and generalised anxiety disorder using self-report retrospective measures; patient health questionnaire 9 (PHQ-9) and generalised anxiety disorder 7 (GAD-7) (Delgadillo et al., 2012a, Delgadillo et al., 2011, Delgadillo et al., 2012b, Fann et al., 2005).

The electronic healthcare record in UK community drug and alcohol teams could provide a prompt to conduct TBI screening if associated clinical markers have been identified (Tan, 2009, Lowenstein et al., 2009). Detecting common mental health problems in patients receiving community drug and alcohol treatment could be a prerequisite for the implementation of the head injury survey application enabling staff to manage risk with this complex patient group.

7.4.2 Domestic violence

Drug and alcohol use is a risk factor for head trauma and domestic violence (Corrigan et al., 2003). In the US, symptoms associated with neurological disabilities from domestic violence frequently remain undetected until the patient receives drug and alcohol treatment (Corrigan et al., 2003). Corrigan et al. (2003) recommended the early detection of TBI with a simple screening instrument to identify women who have experienced head trauma from domestic violence. The two female patients who participated in this study were both subjected to domestic violence. The violent trauma events were highly distressing for the patients and the preference was to complete the head injury survey with a trusted member of staff from the community drug and alcohol team.

7.4.3 Violent assault

A history of drug and alcohol use is associated with violent assault (Drubach et al., 1993). Procuring illicit substances for one patient led to hospitalisation following a violent assault. A study by Kraus et al (1989) found 1155 patients admitted to hospital for head trauma had positive blood alcohol levels at the time of injury. Heavy alcohol use is a reliable predictor for physical confrontation (Chermack and Blow, 2002). Staff in community drug and alcohol teams routinely measure self-reported drug and alcohol use with the Treatment Outcomes Profile questionnaire (Marsden et al, 2008) combined with onsite urinalysis and breath alcohol level testing (Kilpatrick et al., 2000).

7.4.4 Armed forces

Patients who have served in the armed forces may be reluctant to disclose past head injuries (Brenner et al., 2015). Findings from this study suggested the rank of the veteran could be a factor in their willingness to share the extent to which head trauma has impacted on their life. A cross sectional survey of veterans accessing primary care found there was a low disclosure rate of veterans sharing post-deployment experiences with their physicians (Chermack and Blow, 2002). The experience of stigma in sustaining head trauma combined with minimisation of the need for care could be a major obstacle to TBI screening for high ranking veterans. Despite there being a considerable amount of literature recording the medical and psychosocial implications of veteran's exposure to head trauma the relationship between TBI and associated problems and symptoms has received minimal attention in UK public health promotion (See section 7.7 Implications for policy, practice and regulation).

7.4.5 Administering the head injury survey application

Involving family members in TBI screening, with patient consent, could be beneficial in distinguishing changes in neurobehavioral functioning pre- and post-head injury. Staff were receptive to the involvement of family and friends when conducting TBI screening. The staff member needs to have a good working alliance with the patient and the involvement of family members in screening for TBI should be advocated. In this study patients with suspected neurodisability required support with tasks, social judgement, emotion regulation and frequently relied upon their family and friends when living with TBI. Robust social networks are positively associated with optimising recovery from TBI (Tomberg et al., 2005).

A note of caution is signified in the literature about the inclusion of family support as research has revealed this caregiving group to be a burdened, depressed and anxious population (Leibach et al., 2014, Gulin et al., 2014, Perrin et al., 2013, Wells et al., 2005). Carers for patients with TBI are vulnerable to secondary traumatic stress through indirect exposure to traumatising events (McCann and Pearlman, 1990). A patient who served in the armed forces questioned the utility of family involvement in TBI screening. He predicted family would interpret changes in mood and behaviour as

a consequence of mental health trauma from serving in the armed forces and not head injury.

7.4.6 Low educational attainment and user interface design

Low reading and writing ability specifically presented usability issues for the patient group that took part in this study. Lower educational attainment is associated with TBI from violent aetiology and three out of four patients who took part in the study had difficulties reading on screen text (Schopp et al., 2006). Schopp and colleagues (2006) found patients who experienced violent TBI had 'low average' reading scores using the Wide Range Achievement Test (Wilkinson, 1993). Comparatively, patients with non-violent TBI had average reading scores. Schopp et al. (2006) hypothesize low reading ability is a long-standing issue for patients with violent TBI rather than a functional consequence of head trauma.

The available usability literature purports multiple barriers to technology access for students with low educational attainment (Wehmeyer et al., 2004). User interface design frequently does not account for the cognitive ability of patients with low reading ability or the wider characteristics associated with violent TBI (Doherty et al., 2000). Mobile device complexity is a usability barrier for patients with low educational attainment. Impairments in language, reasoning, information processing, memory and learning present unique challenges for user interface design. Neurological deficits could make it difficult to generalise learning from one experience of technology to another.

7.4.7 TBI screening summary

TBI is frequently a consequence of violence (Hanks et al., 2003). Veterans, domestic violence, common mental health problems and severe substance dependence are associated with violent head trauma and can serve as important clinical markers for staff. Patient disclosure of past traumatic events relating to violence presents different challenges for staff administering the head injury survey. Staff must build trust and create a space in which patients can disclose distressing thoughts and feelings (Morse, 1990) as the experience of recalling past traumas can be upsetting. The instrument

needs to be sensitive to staff values in promoting a helping relationship in which they can engage with their patients. Routine TBI screening in community drug and alcohol teams with the involvment of family could begin to foster more open disclosure and instigate a dialogue with at risk TBI patient groups (Zeber et al., 2010).

7.5 Application programming interface implications for development

In mobile application development, several considerations need to be made; development cost, mobile platform, operating system upgrades, software licencing and type of mobile device (NHS Innovations South East, 2014). Developing a health application can be expensive depending upon the complexity of the design. Development costs can range from £1,000 for a basic application to more than £30,000 for a multi-feature application (NHS Innovations South East, 2014).

In this study access to internal software development resources was not available and the software application programming interface (API) had to be outsourced. Snap Mobile Anywhere (Snap Surveys Ltd, 2016) provided the tools to generate online questionnaires and offered a pragmatic low cost solution to digitising a customisable user interface. It had the flexibility to operate on three mobile platforms; Google Android, Apple iOS and Microsoft Windows. For licensed Snap users, free upgrades were available in response to developments in mobile platform operating systems. Snap Mobile Anywhere (Snap Surveys Ltd, 2016) could be used on a range of devices including mobile phones, tablets and desktop computers. Despite these benefits, Snap Mobile Anywhere (Snap Surveys Ltd, 2016) was a significant compromise in restricting the final design for usability evaluation. The synchronous connection to a remote secure server had strengths and limitations. No confidential data was stored locally to the device. This is an important consideration as patients receiving drug and alcohol treatment may frequently lose or sell their phones. However, the tablet computer had a weak Wi-Fi connection causing slow screen changes and unresponsive item selection. Staff required an instrument which facilitated rapport with their patients. Future developments in mobile network telecommunication could make synchronous connections more viable. Ultimately Snap Mobile Anywhere (Snap Surveys Ltd, 2016) is

an API which generates online surveys and could not replicate a clinical interview, the preferred administration method for both patients and staff.

7.6 Strengths and limitations of usability research in community drug and alcohol treatment.

The pragmatic methodology selected for this study complemented the aims and objectives of the research. Stakeholder involvement, cognitive walkthrough and problem discovery analysis resulted in useful insights into patient and staff experience when interacting with the head injury survey user interface. This study marks the first steps in early instrument development and has provided a foundation for future redesign iterations.

In the needs assessment six design criteria were developed for the gap analysis without critical appraisal. Determining the suitability of identified TBI case finders using these six design criteria biased the needs assessment outcome. To increase the rigour of the needs assessment the six design criteria could have been developed using The Practice Guidelines Evaluation and Adaptation Cycle (Graham et al., 2002) rather than exclusively relying upon Williams' (2012) TBI screening recommendations. Graham et al's (2002) framework provides a method for evaluating and adapting practice guidelines in healthcare and could be adopted when refining future practice based design criteria.

In light of the findings from this study 'self-completing and mitigate the need for a trained professional' was perhaps the most controversial criteria. The administration of the head injury survey application was considered to be a potentially distressing intervention by both patients and staff and required the involvement of a trained professional to provide follow up support if necessary. A more comprehensive review of practice guidelines for TBI screening combined with real world observation of practitioners using TBI case finders could have led to design criteria which had greater credibility in screening the suitability of available TBI case finders.

A brief, portable TBI case finder with a user interface which was not dependent upon reading ability was favoured by participants. However, it was not feasible to determine the relevance of developing an instrument which was non-invasive and accessible to a range of service providers from the findings in this study.

A further limitation of the study was the lack of business justification case for the development of the health application. There are three areas of consideration for future development. Firstly, a strategy for training staff in how to administer the head injury survey could be provided. Secondly, a plan could be formulated in how the health application will be sustained in terms of maintenance and updates ensuring clinical content remains evidence informed. Finally, prior to the next phase of usability testing Wi-Fi, mobile device and application capability should be comprehensively assessed.

7.7 Implications for policy, practice and regulation

The findings in this study are unique as they offer an insight into the usability challenges faced by patients who have been exposed to violent head trauma when interacting with health application technology. Designing for neurodisability and associated morbidities has implications for policy, practice and regulation.
The NHS Health Research Authority NRES Committee Yorkshire & the Humber - Leeds West provided ethical approval for this study (REC reference: 14/YH/0139)**.** The NHS had been at the forefront in developing and promoting the Health Apps library. However, the project was discontinued in 2015 following concerns over patient data security (Huckvale et al., 2015). Huckvale et al. (2015) criticised the quality of clinically accredited health applications in the NHS health apps library. The study concluded the dependence upon developers to self-certify compliance to data protection standards was inadequate when managing risk to patients (Huckvale et al., 2015). The trustworthiness of mobile health applications will be eroded if regulation fails to respond to the need to ensure patient privacy when managing personal data (Huckvale and Car, 2014).

Boulos and colleagues (2014) propose the NHS should ensure approved health applications have up to date clinical content which is safe, sound and technically secure. The Food and Drug Administration and the Medicines and Healthcare Products Regulatory Agency classification of health application medical devices has been critiqued for being too narrow and should encompass fitness for purpose, effectiveness and value for money (Boulos et al., 2014). Such changes in regulation would recognise the value of usability, accessibility and readability needs of the target patient group (Boulos et al., 2014).

The usability findings in this study have focused on the cognitive accessibility of the head injury survey, signifying a move away from traditional usability research which typically prioritises visual, auditory and motor accessibility (Boulos et al., 2014). The development foundation for the head injury survey application embodies the future direction of mobile health application regulatory control and certification.

Policy developers for healthcare providers have proposed strategies in how to select and evaluate health applications. Quality of the health application can be demonstrated through evidencing stakeholder involvement and patient user feedback in combination with published peer reviewed research.

The drug and alcohol treatment strategy neglects the prevalent issue of TBI with substance using patients (Great Britain Home Office, 2010). The Advisory Council of the Misuse of Drugs briefing paper (2015) for prevention of drug and alcohol dependence acknowledges how there needs to be a shift from single domain approaches to the delivery of interventions for multiple health behaviours (Hale and Viner, 2012, Prochaska et al., 2008, Werch et al., 2010). The findings in this study reinforce the need to tailor healthcare services to patients with multiple morbidities. It is evident there is no current political appetite for policy development to advocate for people with brain injury in drug and alcohol treatment services in the UK. However, emerging evidence promotes the use of brief TBI screening questions in primary care, recognising the benefit of modest focused efforts in improving positive healthcare seeking behaviour (Kehle et al., 2010).

7.8 Conclusion

Health application development must demonstrate how it provides patient and organisational benefit. This was achieved through ensuring the head injury survey application was connected to NHS clinical drivers. Further usability research is required in the development of the user interface of the head injury survey application to establish whether future design changes have improved usability when optimising the final user interface design. The next design iteration will need to be more responsive to the needs of patients with co-occurring TBI and substance use disorder receiving community drug and alcohol treatment. The instrument will support staff in their continued efforts to meet the complex treatment challenges of their patients. The community drug and alcohol treatment setting is a microcosm of patients with multiple morbidities who present with chronic health issues. The clinical decision support software could better help coordinate care through providing guidance in how to make specialist referrals to brain injury services and to bridge the treatment gap for patients with head trauma.

8.0 Conclusion

In this chapter a summary and key findings of this study are presented. Recommendations are made for head injury survey user interface improvements. Implications for practice for conducting traumatic brain injury (TBI) screening are offered and recommendations given for future research and development of the head injury survey application.

8.1 Summary

This study developed a head injury survey user interface with embedded clinical decision support software for detecting self or proxy reports of lifetime exposure to TBI. The head injury survey application user interface was adapted from the Ohio State University Traumatic Brain Injury Identification Method (OSU TBI-ID) (Corrigan and Bogner, 2007) and the Department of Health clinical guideline for Head Injury: Assessment and early management (NICE, 2014). The ergonomics of human-system interaction standard (ISO, 2010) offered broad guidance in the planning and management of usability research for this study.

The OSU TBI-ID was identified through scoping the available literature (Bogner and Corrigan, 2009, Corrigan and Bogner, 2007). Two implications for practice were identified; interviewer training demand and administration time. A competitive analysis search was conducted to determine whether an appropriate mobile health application had been developed. None of the health applications identified were screening instruments for lifetime exposure to TBI. Consideration was given to regulatory requirements in early instrument design and development (HRSA, 2006). The area of regulation prioritised in this study focused on the ergonomics of human-system interaction (EC, 1993).

Stakeholder involvement expert reference groups were formed and a paper based prototype user interface was developed following usability design guidelines. To demonstrate features such as scrolling, data entry and use of technology an application programming interface (API) was selected. Technical guidance was received from the University of Leeds in choice of API and cyber security considerations. Snap Mobile Anywhere (Snap Surveys Ltd, 2016) provided the tools to

generate online questionnaires and offered a pragmatic low cost solution to digitising a customisable user interface.

To evaluate the usability of the head injury survey application a concurrent embedded mixed methods design was used (Johnson and Onwuegbuzie, 2004). The mixed methods paradigm emphasis was predominantly qualitative (Morse, 1991). Eight participants were purposively recruited from a community drug and alcohol treatment service; four patients and four staff.

Cognitive walkthrough was used to identify generic usability issues focusing on the participants' cognitive accessibility of the head injury survey user interface. Usability tests were audio recorded and transcribed verbatim. A thematic analysis was conducted and three themes were identified; user interface problems and improvements, living with TBI and high tech or low tech healthcare.

The theme user interface problems and improvements was quantified using problem discovery analysis (Rubin, 1996). Unique usability problems were counted and severity rated within the five predefined user interface categories; navigation, content, page layout, terminology, data entry and technology. Frequency and severity scales were used and their scores combined to produce a criticality score. The higher the score, the greater the redesign priority.

Patients and staff had different head injury survey user interface redesign priorities and rich problem descriptions revealed their unique usability perspectives. Patients found navigating the survey difficult. A combination of neurological deficits, limited IT skills and low reading ability meant three out of the four patients could not complete the head injury survey application. Repetitive questioning and length of the survey caused problems for patients with compromised working memory.

Patients had a limited understanding in how to operate information computer technology. Computer based language and user interface features such as open field boxes restricted data entry. Too much on screen content and small fonts induced fatigue and frustration. Inconsistent page layout made following text based instructions difficult. Long sentences and words with multiple syllables reduced task comprehension.

For staff, data entry and technology was the highest redesign priority. They questioned the validity of the decision support software requesting more transparency in how the head injury survey application made clinical judgements. Staff considered some of the terminology to be stigmatising and too clinical. Staff found survey questions repetitive, restricting how the instrument could be navigated. Too much on screen content and grammatical errors inhibited rapport with their patients.

The theme living with TBI revealed a patient group who had experienced multiple violent head trauma. The head injury survey application needs to be sensitive to the disclosure of domestic violence, physical confrontation and veterans' post deployment experiences. Recollection of past traumatic events can be distressing and the nature of the injuries degrading. Patients may be reluctant to disclose trauma events and self-assessment of injury severity was common. Patients frequently relied upon family and friends' judgement when to seek medical help following head trauma.

The theme high tech or low tech healthcare revealed staff perspectives in how the instrument should be administered. Staff wanted to retain control over the administration of the instrument as they anticipated the head injury survey application could be upsetting for patients. The instrument could facilitate delivery of care, an important requirement for a potentially distressing intervention.

8.2 Recommendations

This section consolidates the usability design recommendations by outlining user interface improvements and implications for practice in conducting TBI screening.

8.2.1 User interface improvements

The next user interface design iteration should incorporate:

- minimal on screen text, large fonts with consistent page layout in a grid formation and eye catching presentation
- labelling to differentiate between on screen instructions and survey questions
- prompts to guide the user to the next task and facilitate enquiry to obtain useful information

- plain English, non-clinical language and reflect the lived experience of sustaining head trauma with non-stigmatising terms
- universal graphical communication combined with screen readers and voice command recognition (Lányi et al., 2012)
- key information visible on screen at all times with reduced navigation (Cole and Dehdashti, 1990, Inglis et al., 2002)
- limited repetition with single choice actions
- administration guidance
- an explanation in how the head injury survey detects TBI
- referral guidance to specialist brain injury services

8.2.2 Implications for practice in TBI screening

Patients should avoid self-completing the head injury survey application as a retrospective measure which encourages the recollection of past traumas can be upsetting. A clinical interview was the preferred administration method for both patients and staff. The tool could be used to enhance delivery of care. Administration of the instrument should be restricted. Electronic healthcare records could provide prompts when to conduct TBI screening if associated clinical markers have been identified. Family members should be involved in the TBI screening process. A balance must be found between conducting a comprehensive TBI screen and avoiding patient fatigue. The head injury survey application needs to have responsive data entry and should be portable using mobile computer technology.

8.2.3 Future research recommendations

This human centred design and evaluation study marks the first step in instrument development for the head injury survey application. Future usability evaluations will need to repeat the instrument design lifecycle incorporating user interface redesign recommendations identified in this study. Future usability testing should be conducted with groups at risk of violent TBI. Technical guidance will be required in selecting an API which is more dynamic and capable of replicating a clinical interview. A universal graphical interface could be developed with experts who specialise in graphical communication for patients with learning disabilities.

Future usability tests should incorporate screen video recording and eye tracking technology to determine areas of focus when completing onscreen tasks. Completion rate, time on task and errors could be useful metrics in evaluating a design when optimising administration time as an important instrument feature. User testing should occur with different hardware devices. Smart speakers are a promising emergent technology which circumvent the need for traditional text based user interfaces. The Google Home assistant and the Amazon Echo use natural language processing and speech recognition, enabling the user to have a conversational interaction with the technology (Munteanu and Salah, 2017).This paradigm shift in hardware mitigates the need for keyboard, mouse and touchscreen display, a useful feature for a patient group with below average reading and writing ability (Munteanu and Salah, 2017).

In future research to establish the reliability and associated risks of the embedded clinical decision support software IEC 62304, the associated standard for medical device software, software life cycle processes (IEC, 2006) should be adhered to. Clinical evaluation methods are available for health application technology and could be used with the head injury survey application (Franko, 2012).

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APPENDICES

Appendix A – Classification criteria Annex IX of Directive 93/42/EEC

▼B

ANNEX IX

CLASSIFICATION CRITERIA

I. DEFINITIONS

1. **Definitions for the classification rules**

1.1. *Duration*

Transient

Normally intended for continuous use for less than 60 minutes.

Short term

Normally intended for continuous use for not more than 30 days.

Long term

Normally intended for continuous use for more than 30 days.

1.2. *Invasive devices*

Invasive device

A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.

Body orifice

Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.

Surgically invasive device

An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.

For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

Implantable device

Any device which is intended:

— to be totally introduced into the human body or,

— to replace an epithelial surface or the surface of the eye,

by surgical intervention which is intended to remain in place after the procedure.

Any device intended to be partially introduced into the human body through surgical intervention and intended to remain in place after the procedure for at least 30 days is also considered an implantable device.

1.3. *Reusable surgical instrument*

Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropriate procedures have been carried out.

1.4. *Active medical device*

Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices. ►M5 Stand alone software is considered to be an active medical device. ◄

1.5. *Active therapeutical device*

Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

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1.6. *Active device for diagnosis*

Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

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1.7. *Central circulatory system*

For the purposes of this Directive, 'central circulatory system' means the following vessels:

arteriae pulmonales, aorta ascendens, arcus aorta, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior, vena cava inferior.

▼B

1.8. *Central nervous system*

For the purposes of this Directive, 'central nervous system' means brain, meninges and spinal cord.

II. IMPLEMENTING RULES

2. **Implementing rules**

2.1. Application of the classification rules shall be governed by the intended purpose of the devices.

2.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices. Accessories are classified in their own right separately from the device with which they are used.

2.3. Software, which drives a device or influences the use of a device, falls automatically in the same class.

2.4. If the device is not intended to be used solely or principally in a specific part of the body, it must be considered and classified on the basis of the most critical specified use.

2.5. If several rules apply to the same device, based on the performance specified for the device by the manufacturer, the strictest rules resulting in the higher classification shall apply.

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2.6. In calculating the duration referred to in Section 1.1 of Chapter I, continuous use means 'an uninterrupted actual use of the device for the intended purpose'. However where usage of a device is discontinued in order for the device to be replaced immediately by the same or an identical device this shall be considered an extension of the continuous use of the device.

▼B

III. CLASSIFICATION

1. **Non-invasive devices**

1.1. *Rule 1*

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

1.2. *Rule 2*

All non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:

— if they may be connected to an active medical device in Class IIa or a higher class,

— if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body tissues,

in all other cases they are in Class I.

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1.3. *Rule 3*

All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

1.4. *Rule 4*

All non-invasive devices which come into contact with injured skin:

— are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates,

— are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent,

— are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.

2. **Invasive devices**

2.1. *Rule 5*

►M5 All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I: ◄

— are in Class I if they are intended for transient use,

— are in Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I,

— are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa.

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.

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2.2. *Rule 6*

All surgically invasive devices intended for transient use are in Class IIa unless they are:

— intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

— reusable surgical instruments, in which case they are in Class I,

— intended specifically for use in direct contact with the central nervous system, in which case they are in Class III,

— intended to supply energy in the form of ionising radiation in which case they are in Class IIb,

— intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,

— intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.

▼B

2.3. *Rule 7*

All surgically invasive devices intended for short-term use are in Class IIa unless they are intended:

▼M5

— either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,

▼B

— or specifically for use in direct contact with the central nervous system, in which case they are in Class III,

— or to supply energy in the form of ionizing radiation in which case they are in Class IIb,

— or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III,

— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.

2.4. *Rule 8*

All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended:

— to be placed in the teeth, in which case they are in Class IIa,

— to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III,

— to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III,

— or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.

3. **Additional rules applicable to active devices**

3.1. *Rule 9*

All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb.

All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.

3.2. *Rule 10*

Active devices intended for diagnosis are in Class IIa:

— if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,

— if they are intended to image *in vivo* distribution of radiopharmaceuticals,

— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.

Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.

Rule 11

All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner:

— that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.

3.3. *Rule 12*

All other active devices are in Class I.

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4. **Special Rules**

4.1. *Rule 13*

All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive ►M5 2001/83/EC ◄, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III.

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All devices incorporating, as an integral part, a human blood derivative are in Class III.

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4.2. *Rule 14*

All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.

4.3. *Rule 15*

All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb.

All devices intended specifically to be used for disinfecting medical devices are in Class IIa. ►M5 Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb. ◄

This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.

4.4. *Rule 16*

►M5 Devices ◄ specifically intended for recording of X-ray diagnostic images are in Class IIa.

4.5. *Rule 17*

All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.

5. **Rule 18**

By derogation from other rules, blood bags are in Class IIb.

Appendix B – Search strategy

Number	Searches	Results
1	prisoners.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	31905
2	homeless.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	21624
3	substance use*.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	81190
4	1 or 2 or 3	131241
5	psychometric.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	96206
6	neuropsychological.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	207722
7	neurobehavioural.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	3358
8	5 or 6 or 7	301921
9	structured interview.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	65983
10	self-report.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	207804
11	9 or 10	269828
12	interrater reliability.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	18234
13	reliability.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	382929
14	correlational.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	53053
15	12 or 13 or 14	433691
16	validity.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	386814

17	predictive validity.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	20382
18	comparison.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	2368073
19	16 or 17 or 18	2719476
20	treatment programs.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	18866
21	facilities.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	231836
22	services.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	1125301
23	20 or 21 or 22	1318858
24	screening questionnaire.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	7873
25	identification method.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	2726
26	24 or 25	10596
27	traumatic brain injury.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	84222
28	tbi.mp. [mp=ti, ab, hw, tn, ot, dm, mf, dv, kw, fs, nm, kf, px, rx, an, eu, pm, ui, sy, tc, id, tm]	52781
29	27 or 28	96615
30	4 and 8 and 11 and 15 and 19 and 23 and 26 and 29	9
31	remove duplicates from 30	3

Appendix C – Sifting Table 1

Journal article	**Decision:** DI, PR, DR
psycINFO	
Bogner and Corrigan (2009)	PR
Corrigan and Bogner (2007)	DR
Embase	
Bogner and Corrigan (2009)	PR
Corrigan and Bogner (2007)	DR
MEDLINE	
Bogner and Corrigan (2009)	PR
Corrigan and Bogner (2007)	DR
Web of Knowledge	
Bogner and Corrigan (2009)	PR
Corrigan and Bogner (2007)	DR

Appendix D – Sifting Table 2

Reference List Hand Search	Decision
Thurman et al (1995)	DI
NCIPC (2003)	DI
Setnik and Bazarian (2007)	DI
Corrigan et al (1997)	DI
Corrigan et al (2003)	DI
Warner et al (2005)	DI
Brooks et al (1997)	DI
Psychological Corporation (1997)	DI
Heaton et al (1993)	DI
Spreen et al (1998)	DI
Bergner at al (1981)	DI
Grace and Malloy (2001)	DI
Corrigan et al (1998)	DI
Jurkovich et al (1995)	DI
Grace et al (1999)	DI
Arrindell et al (2001)	DI
Arrindell et al (1999)	DI
Gough (1994)	DI
Gough (1957)	DI
Megargee et al (1971)	DI
De Francisco and Taylor (1993)	DI
Gough (1987)	DI
Gough and Bradley (1992)	DI
Kadden et al (1996)	DI
McLellan et al (1990)	DI
Winer et al (1971)	DI
Lenneberg (1967)	DI
Ewing-Cobbs et al (2003)	DI
Giza and Prins (2006)	DI

Baguley et al (1997)	DI
Bigler et al (1996)	DI
Jorge et al (2005)	DI
Campbell and Fiske (1959)	DI
Bernstein (1999)	DI
Alexander (1995)	DI
Rees (2003)	DI
Ruff and Jurica (1999)	DI
Binder (1997)	DI
HRSA (2007)	DR
Harrison and Beck (2003)	DI
Diamond et al (2007)	DR

Appendix E – TBI case finder repository table

STATE OR ORGANIZATION	TITLE	SERVICE SYSTEM	TARGET AUDIENCE	RESPONDENT	# OF QUESTIONS	INSTRUC-TIONS INCLUDED?	WEB ADDRESS
Alabama	*Brief Screening for Possible Brain Injury*	Rehabilitation Services	Domestic Violence	Adult Individual	10 with 11 follow-up questions	Yes	**PDF:** http://www.tbitac.nashia.org/tbics/download/AL%20--%20Brief%20Screening%20for%20Possible%20BI.pdf
Alaska	*Screening Tool for Dual-Diagnosis and TBI*	Health & Social Services	Mental Health & Substance Abuse	Adult Individual	40	Yes	**DOC:** http://www.tbitac.nashia.org/tbics/download/AK%20--%20Dual%20Diagnosis%20screening.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/AK%20--%20Dual%20Diagnosis%20screening.pdf
Associated Therapists	*Amen Brain System Checklist*	Mental Health	Mental Health	Adult Individual	114	Yes, minimal	**PDF:** http://www.tbitac.nashia.org/tbics/download/amen_checklist.pdf
Colorado	*Preliminary Screening Tool for Identification of Acquired Brain Injury*	Education	School Aged Children	Parent or Guardian	40	Yes	**PDF:** http://www.tbitac.nashia.org/tbics/download/CO-Prelim_Screening_Tool_and_Guidelines.pdf
Defense & Veterans Brain Injury Center (DVBIC)	*Post Deployment Injury Questionnaire*	Military Medical Center	Soldiers & Veterans	Adult Individual	22		**DOC:** http://www.tbitac.nashia.org/tbics/download/Vets%20--%20Post%20Deployment%20Screening.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/Vets%20--%20Post%20Deployment%20Screening.pdf
Defense & Veterans Brain Injury Center (DVBIC)	*Brain Injury Guideline Reference Card*	Military Medical Center	Soldiers & Veterans	Adult Individual	41	Yes	**DOC:** http://www.tbitac.nashia.org/tbics/download/Vets%20--%20BI%20Guideline%20Ref%20Card.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/Vets%20--%20BI%20Guideline%20Ref%20Card.pdf
Iowa	*Iowa Head Injury Screening Instrument*	Health	Mental Health & Substance Abuse	Adult Individual	14	Yes	**DOC:** http://www.tbitac.nashia.org/tbics/download/IA_screeninginstrument.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/IA_screeninginstrument.pdf
Kansas	*Client, Assessment, Referral, and Evaluation Form; and Training Manual Excerpt*	Aging	Older Adults	Adult Individual or Caregiver	11 with multiple follow-up questions		**PDF:** http://www.tbitac.nashia.org/tbics/download/KS_BI_Screening_Tool.pdf
Maryland	*Brief TBI Screening (Spanish version also available)*	Health & Mental Hygiene	Mental Health & Substance Abuse	Adult Individual	9		**DOC:** http://www.tbitac.nashia.org/tbics/download/MD%20--%20TBI%20Screening-English.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/MD%20--%20TBI%20Screening-English.pdf

STATE OR ORGANIZATION	TITLE	SERVICE SYSTEM	TARGET AUDIENCE	RESPONDENT	# OF QUESTIONS	INSTRUC-TIONS INCLUDED?	WEB ADDRESS
Maryland	*TBI Screening Tip Sheet*	Health & Mental Hygiene	Mental Health & Substance Abuse	Adult Individual	7 with multiple follow-up questions		**DOC:** http://www.tbitac.nashia.org/tbics/download/MD%20--%20Tip%20Sheet%20for%20TBI%20Screening.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/MD%20--%20Tip%20Sheet%20for%20TBI%20Screening.pdf
Michigan	*HELPS Brain Injury Screening Tool*	Community Health	Social Services & Mental Health	Adult Individual	7	Yes	**DOC:** http://www.tbitac.nashia.org/tbics/download/MI%20--%20TBI%20Screening.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/MI_HELPS_BI_Screening_Tool__Instr.pdf
Minnesota	*Identification of Persons with a Traumatic Brain Injury*	Human Services	State Operated Services	Medical Staff	4		**PDF:** http://www.tbitac.nashia.org/tbics/download/MN_TBI_Screen_and_Policy.pdf
Mount Sinai School of Medicine	*Brain Injury Screening Questionnaire (BISQ)*	Multiple	Various	Adult Individual or Parent	113		**WEB PAGE:** http://www.mssm.edu/tbicentral/resources/technical_screening.shtml
National Association of State Head Injury Administrators (NASHIA)	*Traumatic Brain Injury Facts: TBI & Older Adults*	Aging	Older Adults	Caregiver, Service Provider, Family Member	10		**PDF:** http://www.tbitac.nashia.org/tbics/download/tbifactsheet--older%20adults.pdf
New Hampshire	*Screening for Traumatic Brain Injury*	Development-al Services	Mental Health	Adult Individual	9		**PDF:** http://www.tbitac.nashia.org/tbics/download/NH-Screening_Tool.pdf
New Mexico	*Brain Injury Screening Form*	Community Services	Substance Abuse	Adult Individual	6 with 13 follow-up questions		**DOC:** http://www.tbitac.nashia.org/tbics/download/NM%20--%20BI%20Screening%20+CD.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/NM%20--%20BI%20Screening%20CD.pdf
Ohio	*Columbus Public Schools Brain Injury Screen*	Education	School Aged Children	Parent or Guardian	22		**DOC:** http://www.tbitac.nashia.org/tbics/download/columbuspubschoolscreen.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/columbuspubschoolscreen.pdf
Ohio Valley Center for Brain Injury Prevention & Rehabilitation	*TBI Screening*	Prevention & Rehabilitation	Community Professionals	Adult Individual	35		**PDF:** http://www.tbitac.nashia.org/tbics/download/OH%20--%20TBIScreening.pdf
Texas	*Brain Injury Screening*	Health	Health Services	Adult Individual or Parent	80		**PDF:** http://www.tbitac.nashia.org/tbics/download/TX%20--%20BI%20Screening.pdf
Virginia	*Domestic Violence & TBI Tip Card*	Rehabilitative Services	Domestic Violence	Adult Individual	8		**DOC:** http://www.tbitac.nashia.org/tbics/download/vadvtipcard.doc **PDF:** http://www.tbitac.nashia.org/tbics/download/vadvtipcard.pdf

Appendix F – Sifting Table 3

BISQ, the IHISI and the STDD articles	Decision
Dams-O'Connor et al (2012)	DI
Nicholas et al (2012)	DI
Topolovec-Vranic et al (2012)	DI
Constantinidou and Argyrou (2012)	DI
Pasinetti (2011)	DI
Goldin-Lauretta et al (2011)	DI
Farrell et al (2010)	DI
Hirshon et al (2010)	DI
Yuka et al (2010)	DI
Dams O'Connor et al (2010)	DI
Kurtz et al (2010)	DI
Beckworth (2010)	DI
Sacks et al (2009)	DR
Cantor et al (2004)	DI
Olson-Madden et al (2012)	DI
McFadden et al (2012)	DI
Tsaousides et al (2011)	DI
Terrio (2011)	DI
Moore et al (2010)	DI
Slota (2009)	DI
Noonan (2009)	DI
Tsaousides et al (2008)	DI
Walker et al (2007)	DI
Dettmer et al (2007)	DI
Gordon et al (2004)	DI

Appendix G – Ohio State University Traumatic Brain Injury Identification Method Research Version

Version 11.18.09

INSTRUCTIONS

Step 1. Identify injuries that may have included a traumatic brain injury (TBI).

The goal of this step is to help the person recall injuries during their lifetime that *may* have included a traumatic brain injury. You will ask about injuries several different ways in order to jog their memory.

In this step inquire about all injuries, not just those to the head. In the rows numbered 1-12 you will make note of those that involved EITHER of the following:

- an impact to the head or neck
- a mechanism of injury that involved high velocity forces like moving vehicle crashes, falling from more than 10 feet, or being shaken violently.
- Being near an explosion

Do NOT include loss of consciousness *solely* due to a drug overdose, other toxic exposure, cerebral vascular accident (stroke) or loss of oxygen to the brain.
Do NOT include memory loss *solely* due to an alcohol blackout.

For each injury that involved the head or neck, also determine how old the person was when it occurred.

In this step do not be concerned about *whether* a TBI occurred, only if it was possible.

<u>These are questions you will ask to identify potential injuries.</u>

A. "In the last 3 months, have you had an injury for which you received medical attention or should have?"

Medical attention includes hospitalizations, emergency room visits, going to a doctor's office or clinic, or being treated by a healthcare provider (like a nurse, team doctor, or Emergency Medical Technician) away from a hospital or office. By 'should have' we mean that later on you realized the injury was more serious and you should have sought help but did not."

B. "In the last year, have you had an injury for which you received medical attention or should have?"

C. "In the last 5 years, have you had an injury for which you received medical attention or should have?"

D. "Was there any time before the last 5 years when you had an injury for which you received medical attention or should have? Think about when you were a child. Think about incidents you may have been told about when you were a baby."

E. "From any time in your life, are there any injuries you may have forgotten to mention. Think about times you might have been in a car accident, crashed a bike, fell, got hurt playing sports or somebody hit you or shook you hard, or you were exposed to an explosion or blast."

F. (*If in military*) "When you were on active duty did you sustain an injury for which you received medical attention or should have that you have not yet told me about?" Think about times you might have been hit by fragments, bullets, blasts (including IED, RPG, land mine, grenade, etc.), vehicular accidents (including airplane or helicopter), or falls."

Step 2. (Guidelines for the Administrator) Determine if a TBI occurred and what its effects were.

The goal of this step is to elicit the details about injuries to the head or neck, or incidents that involved high velocity forces (i.e., moving vehicle crashes, falls from >10 ft., or being shaken) to determine if there was altered consciousness (i.e., unconsciousness, dazed, confused, memory lapses).

For each injury identified in Step 1 ask: "For the first injury you told me about, remember you said at age ___ you [refer to cause or other description of injury], were you knocked out or did you lose consciousness?" If Yes: ask "For how long?" (put a check mark in the box corresponding to the correct duration: less than 5 minutes, 5 to 30 minutes, more than 30 minutes. **Require the respondent to estimate the duration.** If they cannot estimate after encouragement, enter a check mark in the "unable to estimate" row. **Do NOT include loss of consciousness *solely* due to a drug overdose, stroke or loss of oxygen to the brain.**

If "No" to loss of consciousness, ask, "Did the injury cause you to become dazed or confused, or to forget what happened?" Put a check mark in the dazed or confused, and/or the memory loss rows if they indicate either or both occurred. Be sure to differentiate these altered states from the effects of alcohol or drugs. **The injury must have caused being dazed, confused or having a lapse of memory. Do NOT include memory loss due to an alcohol blackout.**

IF THE INJURY DID NOT RESULT IN LOSS OF CONSCIOUSNESS OR ALTERED CONSCIOUSNESS, THEN DO NOT ASK ADDITIONAL DETAILS ABOUT THIS INJURY. GO TO THE NEXT INJURY.

IF THE INJURY RESULTED IN LOSS OF CONSCIOUSNESS OR ALTERED CONSCIOUSNESS, ASK ABOUT MEDICAL ATTENTION AND SYMPTOMS, AS FOLLOWS:

For each injury then ask "Were you hospitalized as a result of this injury?" If they were, ask "Were you discharged to home (H) a rehabilitation facility (R) or a nursing home (NH)?" and enter the correct letter in the column for that injury. If they were not hospitalized ask "Did you receive any other medical attention?" and check all boxes that apply. Other healthcare provider might include a team doctor, a nurse who was present, or an Emergency Medical Technician who did not take the person to the

Emergency Room. If they received no medical attention, ask “Do you think you should have received care for this injury?” and enter a check mark if they thought they should have.

For each injury then ask “After the injury did you have problems caused by the injury that you did not have before or that got much worse?” Ask about each symptom and place a check mark in the column if the symptom occurred as a result of the injury or was made worse by it. **Generally, we are interested in symptoms that persisted at least several weeks or longer.**

Multiple mild injuries.

In some cases, people who have experienced multiple mild injuries as a result of child abuse, domestic violence, or some sports (boxing and football in particular) may have trouble isolating individual injuries. The interviewer should make every attempt to have the individual identify specific injuries and record them in the grid on page 2. However, if this is not possible, check the “multiple mild” column and indicate the cause of these injuries (e.g., child abuse, domestic violence, boxing). Under age, record the age range during which these multiple mild injuries took place. Under “Altered Consciousness” check the longest duration of lost consciousness or the most typical altered consciousness. Under medical care received record the most intensive medical attention received.

Multiple mild? (if yes, place a check in this column)						
How old were you? (do not leave blank)						
Identifier: _____ **Interviewer:** _____ **Age** _____ Cause of injury: Transportation (TR); Self-inflicted violence (SV); Other-inflicted violence, not blast injury (OV); Blast Injury (BL); Falls (FA); Sports (SP); Other (OT)						
ALTERED CONSCIOUSNESS						
Were you knocked out or did you lose consciousness from this injury? (Y/N)						
If yes, for less than 5 minutes						
5 to 30 minutes						
More than 30 minutes						
Unable to estimate						
[If not knocked out] **Did the injury cause you to become dazed or confused?** (Y/N)						
[If not knocked out] **Did you forget what happened before or after?** (Y/N)						
IF NO LOSS OR ALTERED CONSCIOUSNESS, STOP HERE						
MEDICAL ATTENTION						
Were you hospitalized?						
[If hospitalized] Were you discharged to home (H) a rehabilitation facility (R) or a nursing home (NH)?						
[If not hospitalized] Did you receive any other medical attention?						
Treated in the emergency room?						
Doctor's office or clinic?						
Other healthcare provider?						
Should have received help but did not?						
SYMPTOMS						
After the injury did you have problems caused by the injury that you did not have before or that got much worse? (0=no, 1a=yes, immediate onset but went away, 1b=yes, immediate onset and persists today)						
Headaches?						
Dizziness or balance problems?						
Blurred vision?						
Tiredness/fatigue or sleep problems?						
Seizures?						
Remembering things or solving problems?						
Managing stress or emotional upsets?						
Controlling your temper/irritability?						

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Appendix H – Health application review

Application name	Description
1. Traumatic Brain Injury (TBI)	Provides information on TBI
2. Head Injury Association	Provides information on TBI
3. Neurocritical Care	Medical journal
4. CNS Mobile App	Provides information on TBI
5. TBI prognosis	Tool for calculating TBI prognosis
6. Concussion Coach	Concussion assessment tool with concussion rehabilitation information
7. Coma Scales	Tool providing scales to assess GCS score, intubated patients and degree of disability following single instance head injury
8. mTBI Pocket Guide	Provides information on TBI
9. Glasgow Pro	Tool for assessing GCS score for single injury
10. Neuroscience Nurse	Provides information on TBI
11. Coma scale	
12. ImpactPrCalc	Tool for calculating TBI prognosis
13. HEADways	Provides information on TBI with single injury concussion assessment tool
14. Concussion Smart	Provides information on TBI with single injury concussion assessment tool
15. MedZam Concussion Assessment	Single injury concussion assessment tool
16. R.I.S.K.S	Mild brain injury information tool
17. Concussion Quick Check	Tool for assessing GCS score for single injury
18. FirstResponder Concussion Recognition App	Single injury concussion assessment tool for athletes
19. HeadSafe	
20. SCAT2	Single injury concussion assessment tool for athletes
21. Concussion Awareness	Provides information and articles on concussion
22. Glasgow Coma Scale (GCS)	Tool for assessing GCS score for single injury
23. Pocket TBI	TBI treatment protocol information
24. BICS	Single injury TBI assessment tool
25. Pediatric Scale Glasgow Free	Tool for assessing GCS score for single injury in children
26. Concussion Recognition & Response	Single injury concussion assessment tool
27. GCS	Tool for assessing GCS score for single injury
28. World Rugby Concussion	Provides information on concussion
29. Post Concussion Syndrome	Provides information on post-concussion syndrome

30. HitCheck	Single injury concussion assessment tool
31. Concussion Disease & Symptoms	Provides information on concussion
32. SACTool Beta	Single injury concussion assessment tool
33. FACT Concussion Test	Single injury concussion assessment tool
34. Concussion Management	Provides information on TBI
35. CDC HEADS UP Concussion Safety	Provides information on TBI, concussion and helmet safety
36. ConcuTrak	Single injury concussion assessment tool
37. EBMcalc Neurology	Features GCS score assessment tool
38. Glasgow Coma Scale Score	Tool for assessing GCS score for single injury
39. CP concussion	Single injury concussion assessment tool
40. Concussion Assessment and Response: Sport Version	Single injury concussion assessment tool for sports
41. Concussion Ed	Provides information on concussion
42. Concussion Tracker	Provides information on concussion and tracks athlete injury
43. P.A.C.E concussion	Provides information on concussion
44. Sway – Balance/Reaction Time/Concussion	Single injury concussion assessment tool with recovery tracker
45. HeadCheck	Single injury concussion assessment tool with recovery tracker
46. Concussion2	Single injury concussion assessment tool
47. XLNTBrain Mobile	Tool for assessing GCS score for single injury

Appendix I – Standardised patient character summary

The standardised patient (SP) is male and was born in 1970. He has not served in the armed forces. The SP has not received any injuries to his head or neck in the past three or twelve months. He has received an injury to his head or neck in the past five years on one occasion after being involved in a fight when he was aged 31. He lost consciousness for less than five minutes. No other factors caused the loss of consciousness. The SP did not seek medical help. Immediately after the head injury he experienced a change in eyesight, was more forgetful, had headaches, blurred vision, dizziness and balance problems, sensitivity to light and noise and had difficultly controlling anger. Forgetfulness, headaches and difficulty controlling anger have remained after the head injury.

Second head injury occurred aged ten when he fell down some stairs. He did not lose consciousness. No post traumatic amnesia, however, he did experience dazed, disorientation and confusion. No other factors caused dazed, disorientation and confusion. Received medical care from GP. Immediately after the injury he experienced fatigue, dizziness, sensitivity to light and headaches. No symptoms remained.

Multiple obstacles to psychological care from the viewpoint of addiction service users

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Abstract

Purpose – *The purpose of this paper is to explore addiction service users' experiences of psychological interventions for depression symptoms, with an emphasis on understanding obstacles to engage with treatment.*
Design/methodology/approach – *This was a thematic analysis of semi-structured interviews with ten people who took part in a randomised controlled trial of cognitive and behavioural interventions; four of whom never engaged with treatment.*
Findings – *Five prominent obstacles to access therapy were: memory deficits, becoming overwhelmed by multiple demands and appointments, being housebound due to fluctuations in mental health problems, tendency to avoid the unfamiliar, and contextual life problems related to deprivation and social conflict.*
Research limitations/implications – *The authors note some possible limitations related to overreliance on telephone interviews and interviewers' field notes. The authors discuss the findings in light of epidemiological research, cognitive, behavioural and motivational enhancement theories.*
Practical implications – *The authors propose it is important to recognise and address multiple obstacles to therapy. Offering therapy appointments that are co-located within addiction services and time-contingent to other social/medical interventions may help to address some of these obstacles.*
Originality/value – *The present qualitative results complement the prior experimental research and enrich the understanding of how to maximise engagement with psychological interventions.*

Keywords *Attrition, Depression, Behavioural activation, Addiction, Cognitive behavioural therapy, User experiences*

Paper type *Research paper*

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Introduction

The comorbidity of mental health and addiction problems (dual diagnosis) has garnered attention from researchers, clinicians and policy makers for well over a decade. Efforts to understand these co-occurring problems have led to the development of several descriptive models, of which the "quadrant model" (National Association of State Mental Health Program Directors, 1998) is one of the most well known. This model proposes that mental health problems can be conceptualised along a continuum of severity, as can substance use, ranging from mild to more severe conditions. Thus, several combinations of comorbidity can be observed in clinical practice, such as severe mental disorders with mild substance dependence, common mental disorders with severe substance dependence, etc. Published guidelines covering the various facets and levels of comorbidity underline its considerable economic, personal and social costs (Substance Abuse and Mental Health Services Administration, 2005; Department of Health, 2002; National Institute for Health and Care Excellence, 2011; Substance Abuse and Mental Health Services Administration, 2002). These guidelines commonly urge care providers to

integrate substance use and mental health treatments and to break down barriers to care for this highly disadvantaged clinical population.

Treatment dropout is common in this client group, representing one of the major challenges to sustained and effective care. Around 50 per cent of participants disengage with methadone maintenance treatment within six to 12 months according to a meta-analysis of clinical trials (Bao *et al.*, 2009). Even when people with dual diagnosis can be helped to remain engaged with addiction treatment through an adequate dose of medication (e.g. see Maremmani *et al.*, 2000), they often disengage with psychosocial aspects of care. For example, Hunt *et al.* (2013) reported up to 57 per cent attrition rates in a systematic review of psychosocial intervention trials for substance users with severe mental disorders. In another meta-analysis of cognitive and motivational interventions for depression and comorbid alcohol use, Riper *et al.* (2014) reported between 3 and 40 per cent post-treatment attrition rates. Given the ubiquitous problem of disengagement with psychological and social support, it is important to understand the possible obstacles.

Studies exploring potential barriers to access health and social care services have mostly focused on samples of substance users (not necessarily those with co-occuring mental disorders). This literature highlights the relevance of concerns over losing child custody (Kennedy and Neale, 2002), negative staff attitudes (Copeland, 1997; Neale *et al.*, 2008), difficulty in adhering to strict appointment times (Riley *et al.*, 2002), burdensome appointment arrangements, local availability, travel costs and difficulties, personal ill-health, anxieties about stigma and about accessing support (Neale *et al.*, 2008). Some have commented on self-reported barriers for particular subgroups of people, such as feelings of powerlessness and shame that can impede treatment seeking in socially deprived men (Dupéré *et al.*, 2012). Other studies have highlighted disparities accounted by poverty and ethnicity (e.g. see Alegria *et al.*, 2002; Wells *et al.*, 2001), and barriers related to fear of disclosure and social stigma (Clement *et al.*, 2015). Regarding ethnicity, it has been suggested that heightened fear of stigma and preferences for culturally bound forms of coping may partly explain some individuals' reticence to seek professional help; however, the cultural and social aspects of ethnic variations are not well understood (Snowden and Yamada, 2005).

Amidst the growing literature on factors related to healthcare utilisation, there is hardly any specific research about self-reported barriers that may deter substance users from accessing psychological interventions for mental health problems. Most studies specific to dual diagnosis are framed from the perspective of healthcare providers and focus on the broader multidisciplinary aspects of care provision (e.g. see Drake *et al.*, 2001; Grella and Young, 1998; Ridgely *et al.*, 1990). Many such studies tend to focus on cases with severe mental disorders and addiction problems. Less is known about the adequate utilisation of psychological care by people who experience common mental disorders, of which depression is one of the most prevalent conditions. For example, in a multi-national general population survey, approximately 26 per cent of alcohol-dependent and 35 per cent of drug-dependent cases were diagnosed with comorbid affective/mood disorders (Merikangas *et al.*, 1998). The prevalence of mild through to severe depression cases in clinical samples of substance users is thought to be as high as 40-49 per cent (Delgadillo *et al.*, 2013; Weaver *et al.*, 2003).

Focusing on this gap in the literature, we report on a qualitative study that aimed to explore addiction service users' experiences of psychological interventions for depression symptoms, with an emphasis on understanding obstacles to engage with treatment. According to the quadrant model illustrated in Figure 1, our target population consisted of participants with clinically significant depression symptoms and mild-to-moderate substance dependence.

Methods

Design and context

This study presents a qualitative thematic analysis of semi-structured interviews with people who participated in a phase I randomised controlled trial. The trial aimed to offer psychological interventions for depression symptoms to a group of 50 people accessing community drug and

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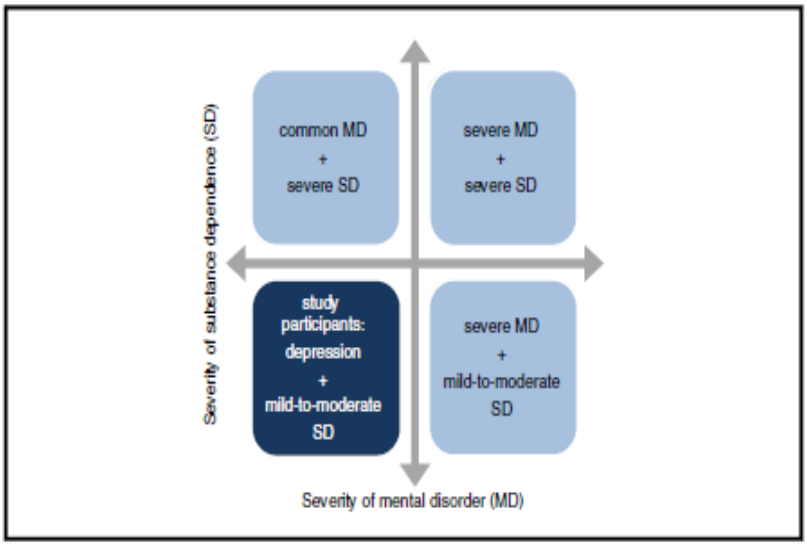
Figure 1 Dual diagnosis quadrant model and study inclusion criteria



alcohol treatment (CDAT) in Leeds, a large city in the north of England. Trial participants meeting criteria for clinically significant depression symptoms (defined based on a score ⩾ 12 on the PHQ-9 measure described below) were randomly assigned to either behavioural activation (BA) delivered by psychological therapists working in a primary care mental health service, or guided self-help (GSH) based on cognitive behavioural therapy principles introduced by CDAT workers. Further details about the trial design, setting, screening tools and interventions can be found in Delgadillo *et al.* (2015).

Sampling, recruitment and data collection

A purposive criterion sampling strategy (Teddlie and Yu, 2007) was applied, aiming to attain variation on two factors: engagement with psychological interventions and gender.

The first factor – engagement – was defined as having attended at least one session of the allocated psychological intervention. Thus, we aimed to interview participants who engaged with the treatments offered as part of the trial, and also those who had the opportunity to access treatment but did not do so. The second factor – gender – was considered based on prior research suggesting that gender differences may influence individuals' readiness to discuss emotional problems and to seek support (Fuhrer *et al.*, 1999).

Participants who consented to take part in the trial were contacted by the study co-ordinator within two weeks after the end of their involvement with a trial intervention. During these contacts, the co-ordinator booked appointments for the participants to have a telephone interview with a researcher. The criteria for end of involvement was met if a participant had: first, never attended any appointments offered within the first four weeks after random allocation to treatment; second, completed their allocated intervention as agreed with their therapist; and third, dropped out of their allocated intervention as evidenced by more than two consecutive missed appointments. Recruitment continued until we completed ten interviews with participants matched to the pre-defined purposive sampling frame.

Telephone semi-structured interviews were conducted and audio recorded by researchers who had no clinical contact with trial participants, and were later transcribed by a research assistant. Interviews were conducted based on a pre-defined topic guide that was split into two parts. Part 1 was only relevant to those who engaged with treatment; the questions aimed to elicit information about the participant's experience of the psychological intervention. Part 2 was only relevant to those who did not engage with treatment; the questions aimed to explore barriers and facilitators to access therapy from the service user's perspective. The interview topic guide is summarised in Table I.

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Table I Interview topic guide

Part 1: for those who engaged with treatment	*Part 2: for those who did not engage*
1. How did you hear about the treatment?	1. How did you hear about the treatment?
2. What made you decide to access the treatment?	2. Was the treatment explained to you before you were offered an appointment?
3. What did you expect from the treatment?	3. What did you expect from the treatment?
4. What did you like/dislike about the treatment?	4. Why didn't you attend the treatment appointment?
5. What did you think was most/least useful about the intervention?	5. Is there anything that would have helped you to take part in the treatment?
6. How do you think the treatment could be improved?	6. Do you think that further treatment is necessary for emotional or mental health issues? (if yes) What kind of help do you think that you need at this point?
7. Did you attend all of the appointments? (prompt: why not?)	
8. Are you still concerned about any symptoms or problems after the treatment?	
9. Do you think that further treatment is necessary for emotional or mental health issues? (if yes) what kind of help do you think that you need at this point?	

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As part of the wider trial, participants were screened using a battery of brief self-reported measures. The primary screening tool was the PHQ-9 (PHQ9; Kroenke *et al.*, 2001). This nine-item questionnaire renders a severity score between 0 and 27, and has been validated as a reliable case-finding tool for clinically significant depression symptoms in substance users based on a cut-off score $\geqslant 12$ (Delgadillo *et al.*, 2011). The GAD-7 questionnaire (Spitzer *et al.*, 2006) was used to assess severity of comorbid anxiety symptoms, with scores ranging between 0 and 21, where a score $\geqslant 9$ indicates clinically significant anxiety (Delgadillo *et al.*, 2012). In order to assess severity of substance dependence, participants completed the SDS measure (SDS; Gossop *et al.*, 1995). This five-item questionnaire yields a total score between 0 and 15, where scores above ten are indicative of severe dependence. Baseline screening data from these measures were also included in the present paper to characterise the subgroup of qualitative interview participants.

Theoretical frame

The philosophical assumptions underpinning this work are routed in a constructivist paradigm (Schwandt, 1994), influencing the chosen research design and method of analysis. This idiographic approach (Denzin and Lincoln, 2000; Filstead, 1979) aims to understand the participant's "lived experience" from the perspective of their constructed reality (Schwandt, 1994, 2000; Sciarra, 1999). This conceptual framework takes the view that reality is constructed in the mind of the individual (Hansen, 2004), within a particular historical and social context (Dilthey, 1977). Based on the above, we assumed that participants' experiences of addiction and psychological treatment were anchored within their wider life and social context.

Data analysis

The analytical strategy complied with the six phases of thematic analysis (Braun and Clarke, 2006). Data analysis was carried out by two researchers who independently reviewed the entire data set of interview transcripts searching for meanings and patterns (phase 1). Next, the analysts generated their own open coding for all data extracts (phase 2). In phase 3, both analysts combined their notes and organised all data extracts and codes into potential emerging themes. In phase 4, themes were reviewed to develop a thematic map with linked codes and extracts across the data set. Phase 5 involved defining and naming each of the themes within an overall coherent narrative. Phase 6 involved producing a narrative report, selecting illustrative extracts that adequately represent the themes and topics covered in the data set.

Results

A total of ten participants were interviewed, the majority of whom were males ($N = 7$) of a white British background ($N = 8$), with a mean age of 39.3 years (range = 25-58). According to the

baseline interviews conducted when participants were recruited into the trial (prior to randomisation, treatment and qualitative interviews), only one participant was abstinent from substance use. The most commonly used substances by this group of participants were heroin ($N = 5$), alcohol ($N = 4$) and cannabis ($N = 3$). Only three participants were poly-substance users. The majority were using opiate substitute medication ($N = 9$) and anti-depressants ($N = 8$). Mean baseline estimates for severity of dependence (SDS = 5.3), depression (PHQ9 = 18.5) and anxiety (GAD7 = 13.4) were generally comparable to those of the total cohort of trial participants ($N = 50$; SDS = 6.1; PHQ9 = 16.9; GAD7 = 11.9). Four interviewees never engaged in any of the trial interventions, four engaged with GSH, and two engaged with BA (Table II).

In what follows, we present a narrative summary of the thematic analysis results. This will be organised into three sections consistent with the interview topic guide. First, we start with an overall analysis of responses regarding how participants learned about the opportunity to access psychological interventions and their expectations about this. Next, we describe the experiences of participants who engaged with the trial interventions. Finally, we conclude with the analysis of responses from those who did not engage with treatment and those who engaged but discussed reasons for dropping out. Quotes from participants are linked to anonymous identifiers which denote a participant number (e.g. P1) along with codes based on our purposive sampling strategy; where M = "Male", F = "Female", DNE = "Did not engage", E = "Engaged".

Participants' experiences of the pathway to psychological care

When asked to remember how they became aware of the opportunity to access psychological interventions, participants ($n = 10$) recalled being encouraged by their drug workers or their

Table II Sample characteristics

Characteristics	*N*
Demographics	
Males	7
Mean age (SD)	39.3 (9.7)
Ethnicity	
White British	8
Other	2
Substances used in the last month	
Alcohol	4
Heroin	5
Crack	2
Cannabis	3
Other	1
Poly-substance use	3
Injecting	1
Abstinent	1
Severity of dependence and psychological symptoms at screening	
SDS mean (SD)	5.3 (3.8)
PHQ-9 mean (SD)	18.5 (4.8)
GAD-7 mean (SD)	13.4 (3.9)
Treatment	
Mean no. of weeks in treatment (SD)	254.4 (130.9)
Using opiate substitute prescription	9
Using anti-depressants	8
Engagement with trial interventions	
Did not engage with psychological intervention	4
Engaged with GSH	4
Engaged with BA	2

Notes: SDS, severity of dependence scale; PHQ9, depression severity measure; GAD7, anxiety severity measure; GSH, guided self-help based on cognitive behavioural therapy; BA, behavioural activation

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doctors. Some associated their recruitment into the study with more overt help seeking on their part ("They suggested it because I told them I was crying uncontrollably"; P3-F-E), while others were more passively monitored and recruited as part of routine screening interviews with a drug worker ("Based on a few scores [referring to depression screening questionnaire] overall the time I've been in treatment, I think not just the one, you know what I mean, as it goes up and down"; P7-F-DNE). At these initial encounters along the pathway to treatment, participants received information about the psychological interventions on offer, and they had a further opportunity to discuss the study with the trial co-ordinator who provided a detailed participant information leaflet. In spite of this, most interviewees reflected a minimal understanding of what the treatments involved ("talking to someone but I think they did something else as well"; P7-F-DNE) and vague recollections about the recruitment process ("I can remember seeing him [referring to the trial co-ordinator] and I signed a piece of paper that he asked me to sign and that's it"; P6-M-DNE). Most interviewees did not know quite what to expect from the interventions ("I didn't know what to expect but wanted help"; P5-M-E), unless they had prior experiences of therapy ("I did have a therapist when I was 10 year old so I had a bit of an idea"; P6-M-DNE).

Although interviewees had unclear expectations about the nature of the interventions, they seemed much more forthcoming about their particular motivations and goals. For example, some were driven to seek treatment by a need to understand the nature of their suffering ("I wanted to know why I was feeling like this"; P3-F-E; "want to know why I'm thinking and why it's happening"; P6-M-DNE). Other explicit goals were to cope better with difficult emotions ("To calm me down"; P6-M-DNE; "To do something about how I'm feeling"; P5-M-E), and to seek alternatives to medication ("I didn't want to go on tablets"; P3-F-E; "giving me tablets, they don't do nought do they, they send you worse"; P7-F-DNE). Many respondents conveyed a sense of desperation, such that they were willing to try any options available ("At the time I was willing to give anything a go"; P1-F-E).

Participants' experiences of psychological interventions

Interviewees asked to reflect about their experience of treatment ($n = 6$, who attended at least 1 therapy session) emphasised the value of having the opportunity to discuss their emotional state, even if this was difficult at times ("she did go into detail about my moods [...] it got emotional towards the end you know"; P3-F-E). Those participants who stated that they derived benefit from treatment attributed this to feeling validated, and to learning about strategies to regulate emotions and to think in a different way ("it validated everything I was feeling and also taught me ways of coping and dealing with how I was feeling"; P9-M-E; "Seeing things from a different perspective"; P1-F-E). Interviewees also commented on the usefulness of having structured and accessible materials supporting the interventions ("The workbook was really helpful"; P9-M-E; "Most useful was the way it was laid out, it was basic but it made sense"; P1-F-E). Reflecting on how therapy helped them, interviewees mentioned feeling less stressed, more optimistic, less concerned about relapse and better able to cope ("I'm loads better than I was, I feel more optimistic about the future and not relapsing"; P1-F-E).

Some participants, however, seemed to derive less benefit from treatment. These participants stated that they were still feeling low in mood and were still struggling with negative thinking and suicidal ideation ("still feeling very low and having thoughts of suicide"; P2-M-E). Another participant did not find the intervention helpful at all, and only recalled that "there was no treatment just forms [*referring to booklets and outcome measures used as part of interventions*]" (P5-M-E).

When asked to reflect on how the interventions could be improved, participants suggested offering a greater number of sessions, longer sessions, follow-up monitoring sessions after the main intervention, and including further information and help to deal with intrusive thoughts.

Participants' views about the barriers and facilitators to access psychological care

All interviewees were asked to reflect on the obstacles that may have got in the way of either starting therapy or continuing to attend appointments after starting treatment. Five general themes emerged from these discussions; these are enumerated below along with illustrative quotes.

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(1) Memory problems

"I completely forgot the appointment. [...] I suffer with depression and I'm not good with remembering things and that, that's why" (P4-M-DNE). "I don't know how I missed it [...]. I'm not sure, I can't remember now" (P6-M-DNE). "I don't remember. [...] I forget as well you know, I forget a lot. [...] I've missed all my appointments" (P7-F-DNE).

(2) Overwhelmed by multiple demands

"I've got that many things going on you see, that many appointments, just got them mixed up with the others" (P4-M-DNE). "I've had all sorts of stuff going on" (P7-F-DNE).

(3) Housebound due to poor mental health

"I wasn't going out the door, I wasn't going nowhere. [...] When I get a bit depressed I don't even go out the door" (P7-F-DNE). "I have panic attacks anyway when I go outside so I try to stay in most of the time" (P6-M-DNE).

(4) Avoiding the unfamiliar

"I don't like going somewhere where I don't know. I get paranoid and that, if I'm going and don't know anybody" (P4-M-DNE).

(5) Contextual events and life problems

"My phone got stolen" (P5-M-DNE). "My boyfriend got locked up for attempted murder" (P7-F-DNE).

When prompted to reflect on how services could make psychological therapy more accessible, participants' responses mostly mapped onto three general themes. Again, these are listed below along with representative quotes.

(1) Help me remember

"Bits of paper just stuck there. That's how I knew you were ringing this afternoon because I can see it in front of me" (P7-F-DNE).

(2) Make it familiar

"I would like to know how many sessions" (P3-F-E). "As long the appointment is at St. Anne's [*referring to her familiar community drug service*] so I know where I'm going" (P4-M-DNE).

(3) Give me appointments that suit me

"Make all my appointments on same day so I can get taxi straight there and back" (P6-M-DNE). "Would have been best to have an early morning appointment as this would have ensured I did that [*attended the therapy appointment*] before I got paid, etc., and could have stopped me using [*referring to buying and using drugs*]" (P8-M-DNE).

Discussion

Strengths and limitations

This qualitative study enabled us to gain insights about the experiences and life context of a group of ten drug and alcohol service users who had the opportunity to access psychological therapy for depression symptoms as part of a clinical trial. Although this study included only one fifth of all trial participants, our purposive sampling strategy achieved variation in participant characteristics with respect to gender, engagement, trial interventions, substances used and poly-substance use. Furthermore, the baseline estimates for psychometric measures in our current sample were broadly comparable to those of the wider trial cohort. Our analysis was conducted by two researchers who initially coded all data independently, later refining the analysis through consensus and peer review, thus ensuring that the analysis and interpretation was not overly influenced by a single reviewer's reading of the data. We consider these sampling and analysis features to add credibility to our findings. On the other hand, a limitation to consider is the study's reliance on telephone interviews, which in some cases made communication difficult (e.g. due to noise, poor signal or interruptions in the participant's home environment) and may have impacted on

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concentration or willingness to discuss private matters. In some cases, the quality of audio recordings was poor, and this forced us to rely on interviewers' field notes, which may have been influenced by recall bias. We also note that the numbers of female respondents ($n = 3$) and cases that did not engage with therapy ($n = 4$) were fairly small.

Reflexivity considerations

Inevitably, our reading and interpretation of the interview data will be coloured by our particular experiences and philosophical orientations. As a group of practicing clinicians, our theoretical reflections are rooted in our particular schools of thought which include counselling psychology, motivational interviewing and cognitive behavioural therapy. Our reflections are also influenced by our grounding in qualitative and experimental research methods and paradigms. Bearing in mind the above strengths, limitations and our particular theoretical orientations, we discuss our main observations with reference to relevant literature.

Theoretical considerations

We learned that people can become linked with psychological care in more active (direct help seeking) or passive ways (being monitored and screened by a professional). Participants hardly remembered any details about their pathway into psychological care, they struggled to articulate their expectations prior to accessing therapy, and many cited forgetting their appointments as a reason for not engaging. The overarching theme of memory deficits comes across clearly in these examples. Memory deficits are commonly associated with depression (Burt *et al.*, 1995). Psychoactive drug use is also associated with deficits in the capacity to learn, store and retrieve new information, so memory is likely to be impaired in dependent drug users (Brown *et al.*, 2000; Solowij *et al.*, 2011; Weinborn *et al.*, 2011). Some interviews suggested that memory problems may have been further compounded by multiple demands and appointments. It is commonplace for dependent substance users to be involved with multiple health and social care providers. For example, data from epidemiological surveys indicate that chronic drug users are more likely to require multiple healthcare interventions, yet they are less likely to receive treatment compared to non-users (Chitwood *et al.*, 1999).

A third theme concerned functional impairment resulting from mental health problems, which left some participants housebound. The interviews suggested that therapy appointments were more likely to be missed during days when depressive mood or anxiety symptoms became exacerbated. This concurs with Neale *et al.* (2008) who proposed that personal ill-health can become an obstacle to healthcare utilisation. Other related themes were avoiding unfamiliar situations and expressing a preference for accessing treatment in known environments. Again, anxiety about treatment seeking has been also highlighted in prior studies (Dupéré *et al.*, 2012; Neale *et al.*, 2008). A notion cutting across these accounts is that of avoidance and safety seeking. Avoidance of distressing stimuli or situations is a common pattern observed in depression and anxiety cases, and indeed it is often a key target for therapeutic change. BA theory, for example, emphasises the need to overcome avoidant tendencies in order to gain a sense of mastery and to increase access to rewarding experiences (Martell *et al.*, 2001). From a cognitive theory perspective, the concept of emotional reasoning denotes a tendency to think in ways that are consistent with fluctuations in emotional states, which in turn can result in avoidant or safety seeking behaviours (Beck and Emery, 1985). From this angle, it is quite understandable that depressed people who are feeling low and negative about themselves may reason that others will judge them in a similarly negative way, especially if they have had prior experiences of discrimination. The desire to access treatment in a familiar setting may possibly reflect a general propensity towards safety seeking behaviours to mitigate emotional distress, and may possibly be a way to deal with the ubiquitous fear of stigma suggested by the wider literature (Clement *et al.*, 2015).

The final theme relating to non-engagement denoted contextual difficulties and life problems. In these interviews, such life problems were associated with poverty, crime and social conflicts. Such issues reflect the complex and disadvantageous life context within which people's addiction and mental health problems are endured. The life stories borne out in these interviews are telling of the social deprivation that is characteristic of many people accessing community drugs and

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alcohol treatment services. Our prior research in this setting, for example, indicated that more than 80 per cent of participants were unemployed and around 11 per cent reported homelessness or acute housing problems (Delgadillo *et al.*, 2011). Our findings also converge with prior studies that describe how substance users with hectic and chaotic lifestyles can struggle to engage with structured treatment programmes and fixed appointments (Riley *et al.*, 2002).

As we expected, some participants derived benefit from therapy and others did not. Interestingly, participants who engaged with therapy recalled limited details about the interventions despite having received copious information and booklets. Those who did recall details generally described procedures which were consistent with cognitive (seeing things from a different perspective) and behavioural interventions (self-monitoring of mood and activities). Beyond these limited details, and given our small sample size, we could not glean any further differences in participants' experiences of both interventions. What was most striking in these accounts was that participants had much better recall for their particular treatment seeking motivations and goals, most of which focused on a need to regulate difficult emotions and to understand the nature of their distress. Furthermore, questions about what people gained from therapy prompted responses congruent with these idiosyncratic goals: feeling better emotionally and things "making more sense". Consistent with Klinger's current concerns theory (Klinger and Cox, 2004), it seems as though, interviewees selectively recalled information that was congruent with their primary concerns and goals, whereas other details were not easily remembered. If we extend this conjecture a little further, it is logical to assume that someone whose current goal is to minimise distress may choose to do so in any number of ways; which could include avoiding stressors, using psychoactive substances, or seeking therapy if the barriers to do so are not seen as insurmountable. Thus, from a motivational interviewing perspective, tilting the decisional balance towards treatment seeking may first require amplifying the salience of personal goals and breaking down a series of obstacles to enhance self-efficacy. The obstacles may include external social and contextual disadvantages, but also internal factors such as memory deficits, reasoning biases, safety seeking and avoidant tendencies.

Implications for policy and practice

In the preceding paragraph we already started to signal a need to recognise and to address multiple barriers to psychological care. Some of the practical suggestions coming from the study participants involved using memory aids/cues, increasing a sense of familiarity with the interventions and treatment settings, planning appointments in such a way as to block or compete with the usual triggers to substance use, and planning time-contingent appointments with different professionals in the same location. In particular, we emphasise the importance of the latter strategy, which we have previously referred to as "co-located care" (Delgadillo *et al.*, 2015). The results of our wider clinical trial indicated that participants offered therapy appointments co-located within the usual (and familiar) community drugs setting were significantly more likely to engage with treatment, compared to participants offered "parallel care" in other (unfamiliar) settings. The present idiographic data suggesting avoidance of unfamiliar settings strengthens the case to fully integrate mental health and addiction interventions within the same team, setting and co-ordinated care plan.

Future developments in policy and clinical guidelines for comorbid addiction and common mental disorders should emphasise the importance of applying structured mental health screening as part of routine addictions treatment, given the well known deficits in this area (Weaver *et al.*, 2003). Clearly, reliable screening is the first necessary step to link people in with psychiatric and psychological support. Our findings highlight the need for such screening practices to be upheld by a care plan that will maximise engagement with mental healthcare. Such care plans would be best placed within the context of addiction services (co-located care), and should include an explicit assessment of possible obstacles (described above) and facilitators to engagement agreed with individual service users. For example, if memory deficits may hinder therapy attendance, the care plan could outline a pre-defined set of memory cue strategies (e.g. text messages, enlisting the help of a family member, etc.) to minimise this problem. This close integration of screening, personalised care planning and psychiatric/psychological interventions can only be achieved if the workforce is adequately skilled in the use and interpretation of validated screening tools and in the delivery of evidence-based interventions. Policy drivers should be designed in such a way that the addiction treatment workforce includes the above skills as part of its core competencies.

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Feasibility Randomized Controlled Trial of Cognitive and Behavioral Interventions for Depression Symptoms in Patients Accessing Drug and Alcohol Treatment☆,☆☆

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ABSTRACT

Depressed mood often co-exists with frequent drug and alcohol use. This trial examined the feasibility of screening, recruitment, randomization and engagement of drug and alcohol users in psychological interventions for depression symptoms. A total of 50 patients involved in community drugs and alcohol treatment (CDAT) were randomly allocated to behavioral activation delivered by psychological therapists ($n = 23$) or to cognitive behavioral therapy based self-help introduced by CDAT workers ($n = 27$). We examined recruitment and engagement rates, as well as changes in depression (PHQ-9) symptoms and changes in percent days abstinent (PDA within last month) at 24 weeks follow-up. The ratio of screened to recruited participants was 4 to 1, and the randomization schedule successfully generated 2 groups with comparable characteristics. Follow-up was possible with 78% of participants post-treatment. Overall engagement in psychological interventions was low; only 42% of randomized participants attended at least 1 therapy session. Patients offered therapy appointments co-located in CDAT clinics were more likely to engage with treatment (odds ratio = 7.14, $p = .04$) compared to those offered appointments in community psychological care clinics. Intention-to-treat analyses indicated no significant between-group differences at follow-up in mean PHQ-9 change scores ($p = .59$) or in PDA ($p = .08$). Overall, it was feasible to conduct a pragmatic trial within busy CDAT services, maximizing external validity of study results. Moderate and comparable improvements in depression symptoms over time were observed for participants in both treatment groups.

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1. Introduction

There is considerable evidence that common mental health problems like depression and anxiety often co-occur with problematic alcohol and drug use (Marsden, Gossop, Stewart, Rolfe, & Farrell, 2000; Strathdee et al., 2002; Weaver et al., 2003). People who frequently use substances are 2 times at greater risk of having a comorbid depression or anxiety disorder, and this increases to 5 times greater risk for dependent substance users (Merikangas et al., 1998). This combination of problems often complicates treatment and can result in greater functional impairment (Johnson et al., 1995), reduced treatment adherence (Carroll, Power, Bryant, & Rounsaville, 1993; Ford, Snowden, & Walser, 1991), poor health outcomes (Hasin et al., 2002; McKay et al., 2002) and increased risk of suicide (Harris & Barraclough, 1997).

The detection of such comorbid disorders has historically been inconsistent in routine treatment in the United Kingdom (Weaver et al., 2003). Consequently, it has been estimated that only 1 in 5 people (20%) involved with community drugs services tend to access mental health treatment (Marsden et al., 2000). Even if comorbid mental health problems are adequately detected, treatment options for this client group seem to have fairly modest benefits. Pharmacological treatments for depression in alcohol and drug users appear to have mixed evidence, with some reviews that indicate a beneficial effect (Iovieno, Tedeschini, Bentley, Evins, & Papakostas, 2011; Nunes & Levin, 2004) and other reviews that question their efficacy (Lingford-Hughes, Welch, & Nutt,

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2012; Pedrelli et al., 2011; Torrens, Fonseca, Mateu, & Farré, 2005). In view of such evidence, exploring the potential of psychological treatments may be a fruitful avenue for research and practice.

Published trials of psychological treatments for depression and anxiety in substance users suggest that cognitive behavioral therapy (CBT) may be an effective treatment (Baillie & Sannibale, 2007; Baker et al., 2010; Brown et al., 2006; Brown, Evans, Miller, Burgess & Mueller, 1997; Hides, Samet, & Lubman, 2010; Hunter et al., 2012; Kay-Lambkin, Baker, Lewin, & Carr, 2009; Kay-Lambkin, Baker, Kelly, & Lewin, 2011; Watkins, Paddock, Zhang, & Wells, 2006; Watkins et al., 2011). There is, however, scarce research on the application of contemporary behavioral activation (BA) models of treatment in clinical populations of substance users. BA is an intervention that alleviates depression by focusing primarily on changing maladaptive behaviors (such as avoidance, rumination, coping strategies that have unintended negative consequences) that are posited to maintain a cycle of low mood (Martell, Addis, & Jacobson, 2001). BA shares some conceptual underpinnings with CBT such as behavior modification and learning theories, but it does not emphasize the direct modification of thoughts and beliefs as in CBT. The efficacy of BA for the treatment of depression in adults has been endorsed by several meta-analyses of clinical trials (Cuijpers, van Straten, & Warmerdam, 2007; Ekers, Richards, & Gilbody, 2008; Ekers et al., 2014; Mazzucchelli, Kane, & Rees, 2009). However, to our knowledge, only one published controlled trial has tested the efficacy of BA with a clinical sample of dependent substance users (Daughters et al., 2008). This trial concluded that augmenting inpatient addiction treatment with BA leads to greater reductions in depression symptoms compared to usual inpatient care.

Considering the prevalence and impact of common mental health problems in drug and alcohol users, and the emerging evidence-base for cognitive and behavioral interventions, we conducted a trial to investigate the feasibility of delivering BA and CBT based guided self-help for depression as part of routine community drugs and alcohol treatment (CDAT). Given our focus on feasibility, the study design also aimed to assess whether co-locating BA within CDAT clinics may enhance engagement with therapy, by comparison to offering this intervention in external mental health clinics as in usual practice. This aspect of the trial was informed by policy guidelines (Department of Health, 2002) that promote integration and close partnership work between substance use and mental health professionals. Although this seems like a sensible policy, we are not aware of empirical evidence specifically supporting the co-location of psychological interventions within CDAT settings and we therefore considered it worthy of further investigation.

2. Methods

2.1. Study design

This was a phase I feasibility randomized controlled trial embedded within CDAT services in Leeds, United Kingdom. Consistent with the medical research council (MRC) guidelines for the development of complex interventions (Craig et al., 2008), the central objective was to examine the feasibility of screening, recruitment, randomization and engagement of patients in psychological interventions for depression symptoms. In this context, we defined engagement as having attended at least one therapy session post-randomization. As part of the design, half of the patients assigned to BA were offered appointments in clinics co-located in CDAT services, and the other half were offered appointments in external clinics—which we refer to as 'parallel' care. A secondary objective was to compare the proportion of cases that engaged with treatment in the co-located versus parallel clinics. Finally, we also aimed to estimate comparative effect sizes to inform the sample size calculation for a fully powered efficacy trial.

Ethical approval for this trial was granted by a National Health Service research ethics committee (REC Reference: 12/YH/0096, Registration: ISRCTN26937594).

2.2. Inclusion criteria

Outpatients accessing five CDAT teams were screened for eligibility to take part in the trial. Patients were included if (a) they were currently registered with CDAT and engaged with these services within the last month; (b) they screened positive for clinically significant depression symptoms as defined by the Patient Health Questionnaire (PHQ-9); (c) they had mild-to-moderate symptoms of alcohol or drug dependence as defined by the Severity of Dependence Scale (SDS). Patients who did not meet the above criteria were excluded from the study, as were those who had a current diagnosis of a psychotic, bipolar, or severe anxiety disorder (this was established based on clinical records, screening tools and interview). People who were in treatment but were free from psychoactive substances (abstinent for at least 4 weeks) were excluded as we were interested in assessing how feasible it may be to recruit and to provide psychological treatment to those who were current and recent substance users.

2.3. Screening, recruitment and randomization

A stepwise screening and recruitment method was applied for 18 months, using the following steps:

(1) All patients currently in treatment in the participating services completed the Treatment Outcomes Profile (TOP) questionnaire as part of regular outcome monitoring.
(2) Those that screened positive for a possible common mental health problem using the TOP psychological health scale (TOP item 4a) were then immediately screened with more specific depression (PHQ-9), anxiety (GAD-7) and severity of dependence (SDS) questionnaires by their case managers.
(3) Those who met inclusion criteria based on step 2 were informed about the study by their case manager and consent to be contacted by the study co-ordinator was obtained.
(4) The contact details of consenting patients were passed on to the study co-ordinator who contacted them to conduct an eligibility and recruitment interview. Informed consent was obtained for participation in the trial at the time of these interviews.

The first 3 steps were conducted in routine practice by the usual case managers and support workers, and step 4 was conducted by the study co-ordinator. The co-ordinator was a researcher with experience in screening and diagnostic assessment, who was not involved in the direct delivery of the trial interventions. In order to minimize the chances that case managers in CDAT teams may be selective about the patients they approached for mental health screening, the study co-ordinator performed regular searches in the clinical database to identify potential participants who had recently completed a TOP questionnaire and who screened positive on TOP item 4a. Electronic reminders were sent (via email and online team calendar) on a weekly basis to case managers to undertake step 2 of the screening method.

Eligible and consenting patients were assigned unique participant codes by the co-ordinator and these codes were then emailed to an independent assistant employed by the National Health Service who performed the random allocation. Randomization was conducted using a computer generated random sequence which was concealed from the clinical teams and the study co-ordinator who undertook recruitment interviews. Participants were either randomized to receive BA or CBT based guided self-help, and this outcome was communicated to clinical administrators who then made contact with participants to offer them a treatment appointment. Outcomes data were collected by the study co-ordinator at 6, 12 and 24 week follow-up to maximize data completeness. This follow-up method ensured that post-treatment outcomes were not collected by the therapists who delivered the intervention. The CONSORT diagram in Fig. 1 summarizes all of the above steps and illustrates the flow of participants through the screening, randomization, treatment and follow-up phases.

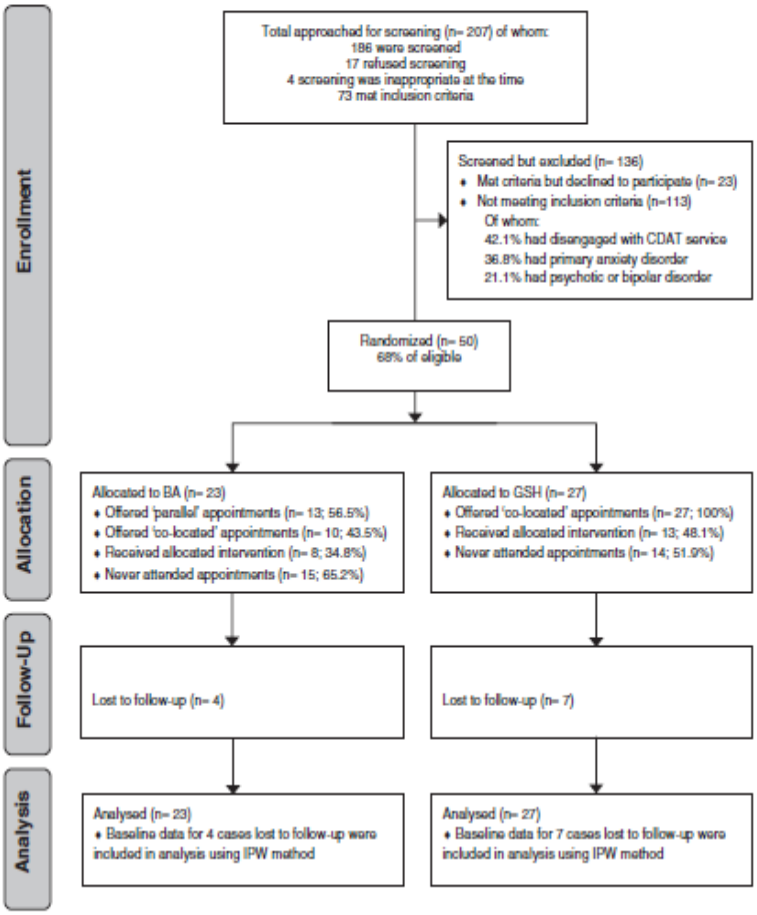

Fig. 1. CONSORT diagram.

2.4. Interventions

2.4.1. Behavioral activation (BA)

A 12-session BA intervention was delivered by qualified (to post-graduate level in structured guided self-help interventions, 1 year supervised clinical training course) and experienced psychological wellbeing practitioners offering low intensity treatments in a Primary Care Mental Health Service aligned to the English *Improving Access to Psychological Therapies* (IAPT) program. BA is a structured intervention for depression based on principles of operant conditioning, functional analysis of behavior and problem solving (Hopko, Lejuez, Ruggiaro, & Eifert, 2003; Martell et al., 2001). Essentially, it consists of: (a) self-monitoring to identify depressive and maladaptive behaviors; (b) graded scheduling of activities aiming to increase and reinforce adaptive behavior patterns; (c) reducing the frequency of avoidant behaviors, rumination and maladaptive coping strategies. The intervention followed a structured treatment manual developed by our collaborators for use in clinical trials of BA (Ekers, Richards, McMillan, Bland, & Gilbody, 2011), with some additional examples and worksheets that are relevant to working with drug and alcohol users (timeline assessment of addiction and emotional problems, decisional balance sheets) drawn from a previous trial of dual diagnosis interventions (Hughes et al., 2008).

BA was delivered in two settings. During the first half of the study, participants assigned to this intervention were offered appointments in primary care mental health clinics across the city (we called this 'parallel' care) as is usual for patients who access the IAPT program. During the second half of the study, new BA participants were offered appointments in clinic rooms that were based within the CDAT services (we called this 'co-located' care). This aspect of the study design enabled us to investigate whether the location of care made any difference to engagement with therapy. For logistical reasons (e.g. the need to obtain and regularly use a clinic room in addiction settings, the impact of travelling on psychological therapists' time and wider caseloads), it was more practical to switch to co-located care halfway through the study, rather than to individually randomize BA participants to parallel vs. co-located treatments.

2.4.2. Guided self-help (GSH)

The GSH intervention was much more minimal in terms of length and intensity, since it involved a single 1 hour session delivered by a non mental health specialist. This involved asking trained case managers employed by CDAT services to provide, describe and encourage participants to apply a self-help booklet for depression based on principles of CBT (Newcastle North Tyneside and Northumberland Mental Health NHS Trust, 2012). In brief, the booklet introduces readers to common thinking biases, thought challenging techniques, self-monitoring and goal setting. The intervention concludes with homework assignments (e.g. to finish reading the booklet and to apply it on a daily basis). All GSH appointments were 'co-located' in usual CDAT clinics.

2.5. Measures

The Patient Health Questionnaire (PHQ-9) was used to screen for symptoms of depression and as a primary outcome measure. This is a nine-item self-completed questionnaire based on the *Diagnostic and Statistical Manual* (*DSM-IV*) diagnostic criteria for major depressive disorder (Kroenke, Spitzer, & Williams, 2001). Each item is rated on a 0 to 3 scale relating to the frequency of depressive symptoms over the last 2 weeks (0 = 'not at all' to 3 = 'nearly every day'). Scores range from 0 to 27 with higher scores indicating greater severity. A cut-off score ≥12 has been found to have adequate sensitivity (81%) and specificity (75%) for the detection of a current depressive episode in routine addiction treatment; the measure also has reliable temporal stability (ICC = .78) in this setting which supports its use for outcome monitoring (Delgadillo et al., 2011).

Given that anxiety symptoms commonly co-occur with depression and impact on clinical outcome (Barlow, 2002), we also included the seven-item GAD-7 questionnaire (Spitzer, Kroenke, Williams, & Lowe, 2006) to screen potential participants for a severe anxiety disorder which may render them ineligible for the trial interventions. The GAD-7 is scored in the same way as the PHQ-9, with a range between 0 and 21. This scale has been established as a valid and reliable case-finding measure for a variety of anxiety disorders in alcohol and drug users using a cut-off ≥ 9 (Delgadillo, Payne, et al., 2012).

The Treatment Outcomes Profile (TOP) is a validated questionnaire that captures information about substance use in the last 4 week period using the timeline follow-back method (Marsden et al., 2008). This questionnaire is routinely applied at regular intervals (e.g. 3 months) to monitor outcomes in addiction services (National Treatment Agency for Substance Misuse, 2012). The TOP also includes a brief psychological health scale (TOP item 4a) that has been demonstrated to reliably detect the presence of a diagnosable common mental disorder (cut-off ≤ 12, sensitivity = 83%, specificity = 71%) when compared to a structured diagnostic interview (Delgadillo, Payne, Gilbody, & Godfrey, 2013).

Severity of dependence to the primary drug used was assessed using the 5-item Severity of Dependence Scale (Gossop et al., 1995) which has been widely validated as a reliable case-finder for substance use disorders (Castillo, Saiz, Rojas, Vazquez, & Lerma, 2010; Kaye & Darke, 2002; Lawrinson, Copeland, Gerber, & Gilmour, 2007; Swift, Copeland, & Hall, 1998). This scale renders a continuous severity score ranging from 0 to 15, where a score of 0 to 10 denotes mild-to-moderate psychological dependence.

2.6. Training and supervision

Qualified BA therapists accessed 2 training days delivered by practitioners with expertise in behavior therapy (DE) and dual diagnosis (JD, LH), and had access to group and individual supervision (led by JD; 2 hours every 6 weeks) which was additional to their weekly clinical supervision in primary care. CDAT workers who delivered GSH accessed a half day training event with a counseling psychologist (SG) who also led their supervision group (1.5 hours every 6 weeks). All therapists were required to keep written records of sessions, which were inspected by the relevant supervisors. Due to limited study resources, no additional fidelity checks (such as independent analysis of recorded sessions) were possible.

2.7. Data analysis

2.7.1. Feasibility analysis

Screening, recruitment, random allocation and treatment engagement data were summarized using a CONSORT diagram (Fig. 1). In order to assess the integrity of randomization, demographic and clinical characteristics were compared between groups using chi-square tests for categorical variables, t-tests for normally distributed continuous variables and non-parametric Mann–Whitney U-tests for continuous variables with skewed distributions.

To quantitatively assess the feasibility of screening, recruitment and successful treatment, we estimated the number needed to screen (NNS) in order to obtain one additional recruit, and the number needed to treat (NNT) in order to attain reliable and clinically significant improvement with one patient. We were also interested in exploring potential predictors of engagement with psychological interventions, which was defined as having attended at least 1 therapy appointment. To this end, we applied multivariate logistic regression models predicting engagement (coded = 1) versus non-engagement (coded = 0), using backward elimination of variables with an alpha level of $p > .05$. Backward elimination was considered appropriate given the small number of participants and hence the likelihood that sample power would be insufficient to apply models that control for several variables. Potential predictors were demographics (age in quartiles, gender, ethnicity), treatment group (BA vs. GSH), appointment modality (co-located vs. parallel care), baseline symptom severity (PHQ-9, SDS), and baseline substance use variables (use of opiate substitute medication, percent of days abstinent in the last 4 weeks, binary marker for poly-substance use). Goodness-of-fit in these analyses was assessed using the Hosmer–Lemeshow test and by examining residual plots.

2.7.2. Secondary analyses

The outcome variable, change in the severity of depression symptoms (PHQ-9) at endpoint follow-up, was compared between groups using analysis of covariance (ANCOVA). Since we expected difficulties with attrition and follow-up as is common in routine addiction treatment, the study design with multiple follow-up assessments enabled us to use the last available assessment as the endpoint for each participant (applying a *last observation carried forward* method). PHQ-9 change scores were taken as the dependent variable in ANCOVA models. Change scores were calculated as the baseline minus the endpoint measure to make interpretation more intuitive, such that a positive score denotes improvement and a negative score denotes deterioration in depression symptoms. Group (BA vs. GSH) was entered as a fixed factor; baseline PHQ-9 score, age (categorized into quartiles), gender and time were entered as covariates. The time variable denoted the time interval (in weeks) between the baseline and final available measurement for each participant, which was variable considering differences in attrition and follow-up. The main analysis was conducted based on *intention-to-treat* principles. To account for cases with completely missing follow-up data ($n = 11$; 22.0%), inverse probability weighting (IPW) was used in the ANCOVA model as a sensitivity analysis. IPW has been recommended as an appropriate method to minimize bias that is common in complete-case analysis and is often preferable to multiple imputation (Hernán & Hernández-Díaz, 2012; Seaman & White, 2013). Between-group differences were estimated, both in terms of mean and adjusted PHQ-9 change scores and as standardized effect sizes (Cohen's *d*). Within-group effect sizes were also calculated using the method proposed by Minami, Serlin, Wampold, Kircher, and Brown (2008); this estimate is comparable to Cohen's *d*, computed for repeated measures and weighted by sample size.

Reliable and clinically significant improvement (RCSI) rates were calculated following the criteria proposed by Jacobson and Truax (1991) and based on a PHQ-9 reliable change index (≥7) and cut-point (<12) calibrated for clinical samples of alcohol and drug users (Delgadillo, 2012). Between-group RCSI rates were compared using chi-square analysis.

Changes in substance use (measured with TOP) were explored by estimating percent of days abstinent (PDA) over the last 4 weeks for each case. Endpoint PDA change scores were calculated as described above and taken as the dependent variable in ANCOVA; with group as a fixed factor; and controlling for age (quartiles), gender, time, baseline SDS and baseline PDA. In this analysis, a negative change score would denote a reduction and a positive score would denote an increase in

Table 1
Sample characteristics and comparisons between randomly assigned groups.

	Full sample $N = 50$ (100%)	BA $n = 23$ (46%)	GSH $n = 27$ (54%)	Test statistic	p
Demographics					
Males	34 (68.0)	18 (78.3)	16 (59.3)	$\chi^2(1) = 2.06$	.15
Mean age (SD)	37.2 (6.6)	38.4 (6.2)	36.2 (6.8)	$t(48) = 1.23$	.22
Ethnicity					
White British	36 (72.0)	16 (69.6)	20 (74.1)	$\chi^2(1) = 0.13$	.72
Other	14 (28.0)	7 (30.4)	7 (25.9)		
Substances used in the last month					
Alcohol	25 (50.0)	14 (60.9)	11 (40.7)	$\chi^2(1) = 2.01$	.16
Mean units per week (SD)	42.9 (56.4)[a]	53.9 (73.3)[a]	30.9 (30.0)[a]	$U(23) = 61.00$	.76
Heroin	17 (34.0)	5 (21.7)	12 (44.4)	$\chi^2(1) = 2.85$	.09
Mean g. per week (SD)	.29 (.33)[a]	.15 (.13)[a]	.34 (.37)[a]	$U(16) = 32.50$	.27
Crack	11 (22.0)	3 (13.0)	8 (29.6)	$\chi^2(1) = 1.99$	.16
Mean g. per week (SD)	.19 (.13)[a]	.10 (.00)[a]	.22 (.14)[a]	$U(11) = 19.50$	.09
Cannabis	11 (22.0)	6 (26.1)	5 (18.5)	$\chi^2(1) = 0.42$	.52
Mean spliffs per week (SD)	10.3 (9.4)[a]	7.7 (10.3)[a]	13.4 (8.1)[a]	$U(11) = 22.50$	.17
Other substances	4 (8.0)	4 (17.4)	0	–	
Poly-substance use	18 (36.0)	7 (30.4)	11 (40.7)	$\chi^2(1) = 0.72$	.40
Injecting	6 (13.6)[b]	3 (15.0)[b]	3 (12.5)[b]	–	
Abstinent	9 (18.0)	4 (17.4)	5 (18.5)	–	
Severity of dependence and psychological symptoms at screening					
SDS mean (SD)	6.1 (3.7)	7.3 (3.8)	5.1 (3.4)	$U(50) = 202.00$	**.03**
PHQ-9 mean (SD)	16.9 (4.3)	17.61 (4.7)	16.4 (4.0)	$t(48) = -0.95$	.35
GAD-7 mean (SD)	11.9 (4.7)	12.3 (4.0)	11.6 (5.3)	$t(48) = 0.50$	.62
TOP-4a mean (SD)	8.5 (3.5)[b]	8.7 (3.6)	8.3 (3.4)[b]	$t(47) = 0.39$	.70
Treatment					
Mean no. weeks in treatment (SD)	195.3 (119.1)[b]	202.9 (126.5)[b]	189.3 (115.1)[b]	$t(43) = 0.38$	.71
Using opiate substitute prescription	46 (92.0)	21 (91.3)	25 (92.6)	–	
Using antidepressants	32 (64.0)	14 (60.9)	18 (66.7)	$\chi^2(1) = 0.18$	.67
Engaged with trial intervention[c]	21 (42.0)	8 (34.8)	13 (48.1)	$\chi^2(1) = 0.91$	.34

t = Student's t-test; U = Mann-Whitney U test; χ^2 = chi-square test; – denotes missing estimates due to violation of test assumptions.
[a] Estimates exclude abstainers from each substance.
[b] Estimates exclude missing data.
[c] Refers to participants who attended at least 1 session of allocated intervention.

substance use. Associations between PDA and PHQ-9 change scores at follow-up were explored using Pearson's correlations. Conventional assumptions for ANCOVA analyses were verified using formal tests assessing homogeneity of variance and by inspecting residual plots.

3. Results

3.1. Sample characteristics and feasibility

As shown in Fig. 1, a total of 207 patients were approached for mental health screening during an 18 month period, based on their response to the TOP (item 4a) questionnaire which indicated that they potentially met criteria for a common mental disorder. More detailed screening using PHQ-9 was feasible with 186 patients (89.9% of 207), out of whom 73 (39.2% of screened cases) met criteria for the study but only 50 (68.5% of eligible cases) consented to participate. Based on these observations, we estimate that it is necessary to screen 4 patients to successfully recruit and randomize one consenting and eligible participant (207/50 = 4.14 = number needed to screen).

Consenting participants were mostly white British (72.0%) males (68.0%), with a mean age of 37.2 (SD = 6.6), most of whom were currently prescribed opiate substitute medication (92.0%) and antidepressants (64.0%). The most commonly used substances in this sample were alcohol (50.0%), heroin (34.0%), crack (22.0%) and cannabis (22.0%). Table 1 presents detailed sample characteristics and demonstrates that there were no significant differences between the BA ($n = 23$) and GSH ($n = 27$) groups in any of these characteristics, except for mean baseline SDS which appeared to be higher in the BA group; $U(50) = 202.00$, $p = .03$. Importantly, there were no significant differences in baseline PHQ-9 between those who provided follow-up data (mean = 16.72, SD = 4.48) and those who did not (mean = 17.91, SD = 3.75); $t(48) = -0.80$, $p = .42$. There were no significant differences in mean PDA estimates between participants who were followed-up (mean = 0.38, SD = 0.38) and those who were lost to follow-up (mean = 0.19, SD = 0.24); $t(26) = 1.96$, $p = .06$. Overall, the randomization process successfully produced two groups with comparable baseline characteristics, and there was no evidence of bias introduced by cases lost to follow-up.

Only 21 participants (42.0%) actually engaged with their allocated intervention (defined as attending at least one session). There were no significant differences in engagement between the BA ($n = 8$; 34.8%) and GSH ($n = 13$; 48.1%) groups; $\chi^2(1) = 0.91$, $p = .34$. Those who engaged with BA attended a mean number of 3.13 sessions (SD = 1.73, mode = 5). A closer examination of the group of BA participants that engaged in treatment revealed that those offered co-located care ($n = 5$; 62.5%) attended a higher mean number of total therapy sessions (mean = 4.20, SD = 1.10) compared to those offered parallel care ($n = 3$, 37.5%, mean = 1.33, SD = .58); however the small numbers did not allow us to apply formal tests of statistical significance. All of those who engaged with GSH had only 1 session (as per protocol), except for one participant who required 2 sessions to work through the self-help booklet due to obstacles with concentration and literacy. We explored potential predictors of engagement using multivariate logistic regression. The final logistic regression model reached through a two-step process of backward elimination of variables is presented in Table 2. According to this model, poly-substance users were significantly less likely to engage with therapy (odds ratio = .15, $p = .02$) and patients offered 'co-located' appointments in a CDAT clinic (who accessed GSH or co-located BA) were at least 7 times more likely to engage compared to participants offered BA in general primary care mental health clinics (odds ratio = 7.14, $p = .04$).

3.2. Depression symptom outcomes

The intention-to-treat (ITT) ANCOVA analysis predicting change in depression symptoms (PHQ-9) at follow-up found no significant main

Table 2
Step-wise logistic regression modelling strategy to identify predictors of engagement[a] with psychological interventions.

Variable	Step 1				Step 2			
	Pseudo R^2 = .45				Pseudo R^2 = .35			
	B	SE	β	*p*	*B*	SE	β	*p*
Constant	−23.59	28235.63	<.001	.99	−1.42	1.15	.24	.22
Gender[b]	1.34	1.26	3.82	.29	.53	.82	1.70	.51
Age lowest quartile (≤32)				.60				.77
Age quartile 2 (33–36)	-.28	1.52	.76	.85	-.09	1.02	.92	.93
Age quartile 3 (37–43)	1.65	1.54	5.19	.28	.27	1.01	1.31	.79
Age quartile 4 (≥44)	.99	1.45	2.69	.50	1.07	1.17	2.90	.36
Poly-substance use[b]	−2.35	1.18	.10	.04	−1.90	.79	.15	.02
Modality[b]	3.47	1.73	31.98	.04	1.97	.98	7.14	.04
Psychological treatment group[b]	1.26	1.53	3.53	.41				
Ethnicity[b]	−1.40	1.45	.25	.33				
Opiate substitute treatment[b]	19.37	28235.63	258202165.3	.99				
Baseline PHQ-9	.03	.14	1.03	.82				
Baseline SDS	.01	.15	1.01	.97				
Baseline PDA	1.22	1.51	3.39	.42				

[a] Engagement is defined as having accessed at least one session of the allocated intervention; step 1 entered all potential predictors of engagement, while step 2 presents a more parsimonious model in which non-significant predictors were removed by backward elimination.
[b] Reference categories: gender = male; age = lowest quartile; poly-substance use = non poly-use; modality = parallel care; psychological treatment group = CBT guided self-help; ethnicity = white British; opiate substitute treatment = not using; β = odds ratio.

effects for treatment group after controlling for covariates; $F(1, 33) = .29$, $p = .59$. The sensitivity analysis applying inverse probability weighting (IPW) to assess the influence of missing data also confirmed the same result; $F(1, 33) = .06$, $p = .81$. Only baseline PHQ-9 was a significant predictor of change in depression symptoms in the ANCOVA models; ITT model, $F(1, 33) = 8.89$, $p < .01$; IPW model, $F(1, 33) = 9.66$, $p < .01$. Table 3 presents unadjusted and adjusted mean estimates of PHQ-9 change scores for each group. The mean difference −1.06 (95% CI = −5.05, 2.92) reflects an approximate between-groups effect size of $d = -0.64$ favoring GSH, although this was not statistically significant ($p = .59$). Baseline and endpoint mean scores and standard deviations reported in Table 3 were used to estimate within-group effect sizes weighted by sample size; these were $d = .49$ for BA and $d = .63$ for GSH. The proportions of patients meeting criteria for reliable and clinically significant improvement (RCSI) were 11.8% for BA and 22.2% for GSH, although differences were not statistically significant; $\chi^2(1) = 0.67$, $p = .41$. The overall proportion of participants meeting RCSI criteria across both treatment groups was 17.1%, and the approximate number needed to treat in order to obtain full recovery with one patient was 6 (NNT = 5.83).

3.3. Substance use outcomes

The ITT ANCOVA model predicting change in percent of days abstinent (PDA in the last month) at follow-up found no significant main effects for treatment group after controlling for covariates; $F(1, 28) = 3.32$, $p = .08$. This finding was corroborated by the IPW ANCOVA model; $F(1, 28) = 3.82$, $p = .06$. Baseline PDA significantly predicted changes in endpoint PDA estimates in the ANCOVA models; ITT model, $F(1, 28) = 12.10$, $p < .01$; IPW model, $F(1, 28) = 10.29$, $p < .01$. The mean difference shown in Table 3 was .25 (95% CI = −.03, .52), which reflects an approximate between-groups effect size of $d = 1.52$ favoring BA, although this was not statistically significant ($p = .08$). Baseline and endpoint estimates reported in Table 3 were used to calculate within-group effect sizes weighted by sample size; these were $d = .40$ for BA and $d = .02$ for GSH. No significant associations were found between PDA change and PHQ-9 change scores at follow-up; $r = 0.10$, $p = .57$.

4. Discussion

4.1. Main findings

This phase I feasibility trial applied a high volume, structured and stepwise mental health screening method to identify CDAT patients with clinically significant depression symptoms. Based on this strategy, the ratio of screened to recruited patients was 4 to 1. Our results demonstrated the integrity of the random allocation method and it was possible to follow up 78% of study participants post-treatment. Overall, it was feasible to conduct a trial embedded within busy clinical settings, maximizing the external validity of the study design. A noteworthy aspect of the study design is the demonstration that high volume screening of mental health problems can be feasibly embedded within routine CDAT services, and linked with evidence-based psychological treatments. The first point potentially offers an important advance, since consistent and reliable mental health screening is known to be lacking in routine addiction services (Weaver et al., 2003). Our pragmatic approach also

Table 3
Change in depression (PHQ-9) and percent of days abstinent (PDA) in each of the treatment conditions.

Group	Baseline mean (SD)	End-point mean (SD)	Unadjusted mean change score (SE)	Adjusted[a] mean change score (SE)	Mean difference (95% CI)	*p*
Depression (PHQ-9)						
BA (*n* = 19)	17.61 (4.66)	15.21 (5.41)	1.79 (1.48)	1.69 (1.32)	−1.06 (−5.05, 2.92)	.59
GSH (*n* = 20)	16.44 (4.02)	13.80 (5.36)	2.65 (1.20)	2.75 (1.28)		
Percentage days abstinent during the last month (PDA)[b]						
BA (*n* = 15)	.38 (.40)	.55 (.45)	.12 (.13)	.17 (.10)	.25 (−.03, .52)	.08
GSH (*n* = 20)	.30 (.33)	.30 (.34)	−.04 (.08)	−.08 (.08)		

n = denotes the total number of respondents with complete follow-up data per group and outcome of interest.
[a] Adjusted for PHQ-9 baseline severity, age, gender, follow-up time, using intention-to-treat analysis; BA = behavioural activation; GSH = guided self-help based on cognitive behavioural therapy booklet; SE = standard error; CI = 95% confidence intervals.
[b] Note that the PDA estimates denote percentages on a 0-1 scale, for example .38 = 38%.

resembles recent studies aiming to train addiction treatment workers to use screening tools and to offer brief interventions for depressed substance users (e.g. see Lee et al., 2011; Watkins et al., 2006).

The greatest difficulty we encountered was the high attrition rate resulting in poor engagement with treatment. This was in spite of the additional administrative support available to the research team which was used to proactively chase up study participants to try to maximize engagement. Our findings revealed that poly-substance use was a risk factor for non-engagement in this sample. Most poly-substance users in this study were combining heroin and crack-cocaine, which is consistent with research indicating that this combination of drugs is associated with treatment discontinuation (Leri, Bruneau, & Stewart, 2003). However, readers should also consider that other studies have yielded mixed evidence about the associations between treatment attrition and quantity, frequency and type of substance use (e.g. see review by Srark, 1992). It may be that poly-substance use could be a marker for other complex factors that influence engagement with treatment, for example impulsivity, involvement in criminal activity, impairments in social adjustment, etc. Such potential associations warrant further investigation. We also found that offering appointments co-located in the CDAT setting considerably increased the likelihood of engagement. Furthermore, it appears that co-located care may also result in greater number of attended therapy sessions by comparison to parallel care. A possible explanation may be that co-location in a familiar setting minimizes clients' concerns about privacy or stigma related to mental health problems. For instance, concerns about privacy have been previously endorsed by patients as a reason for dropping out of addictions treatment (Ball, Carroll, Canning-Ball, & Rounsaville, 2006). Another possibility is that co-location simply makes access to treatment more convenient, especially if patients may have limited financial resources to travel to various appointments in different locations.

The preliminary outcomes analysis evidenced modest improvements in depression symptoms over time, with moderate within-group effect sizes ($d = .49$ to .63). These effects are comparable in magnitude to the BA trial conducted by Daughters et al. (2008), where the approximate within-group pre–post effect sizes for the BA intervention were $d = 0.49$ for the Hamilton Depression Scale and $d = 0.91$ for the Beck II Depression measure. Considering the wider literature in this area, Hesse (2009) reported aggregated depression symptom effect sizes in the region of $d = -0.58$ (95% CI −1.10 to −0.06) in a meta-analysis favoring integrated psychological and substance use disorder treatments compared to non-integrated control conditions. A more recent meta-analysis (Riper et al., 2014) which specifically focused on integrated CBT and motivational interviewing trials (iCBT) reported a more modest aggregated effect size for depression symptoms favoring iCBT versus usual care ($g = 0.27$, 95% CI 0.13 to 0.41).

As noted by Hides et al. (2010) trials comparing CBT to active control conditions in depressed substance users mostly report non-significant differences. Similarly, we found no significant differences in depression symptom outcomes between groups, which was remarkable considering that the GSH intervention was delivered over a considerably briefer duration (1 session). However, this finding should be taken as preliminary since this study was not sufficiently powered to undertake a non-inferiority analysis. It is also possible that the non-significant differences may be explained by the relatively low number of mean treatment sessions (mean = 3.13, mode = 5) attended by participants in the BA group. We note that the PDA estimate increased by 17% in the BA group after treatment, indicating reduction in substance use, whereas no change in substance use was apparent in the GSH group. This finding requires replication in a larger sample since the mean difference between groups did not reach statistical significance. It nevertheless raises an interesting question about the potential benefit of BA in the reduction of problematic substance use, which is comparable in effect to the average 14.1% PDA gain reported in the meta-analysis by Hesse and collaborators (Hesse, 2009) favoring integrated psychological interventions.

4.2. Implications for practice and research

The psychological care of dependent substance users has historically tended to be a neglected area of practice and research. The present study draws attention to the feasibility of high volume mental health screening, and the co-location of psychological and substance use interventions.

Co-location of mental health and addiction specialists appears to enhance engagement with treatment and is consistent with policy developments urging professionals to co-ordinate care and break down barriers for people with complex needs and co-morbidities (Department of Health, 2002; Mental Health Foundation, 2013). We underline two further points about co-location. First, future trials could investigate whether it is possible to maximize the benefit of co-location by applying principles of contingency management (CM), which involves the provision of incentives (e.g. vouchers, or prescriptions) to enhance treatment adherence. CM has a robust evidence base in addictions treatment and is recommended by clinical guidelines (National Institute for Health and Clinical Excellence, 2007). For example, co-located depression treatment appointments followed by CM specifically aimed to incentivize (a) attendance and (b) abstinence may provide the best possible context to enable patients to self-manage their mental health. Secondly, the parallel care offered in our trial was far more costly and less efficient due to lost clinical time, additional administrative burden invested in chasing participants up and additional clinical time invested in calling and liaising with workers in CDAT services. Future trials and indeed clinical services should consider either co-locating mental health specialists within CDAT units or training and supervising addiction workers to deliver evidence-based interventions for depression symptoms.

4.3. Limitations

The stepwise screening method may have excluded some potentially eligible participants simply due to the limitations of the TOP item 4a scale which was applied as the first step, since some 'false negatives' may have been excluded from screening with PHQ-9. This is a plausible limitation; however, our decision to apply a pragmatic stepwise method is congruent with our prior observations that some patients can find detailed screening intrusive and emotionally challenging (Delgadillo, Gore, et al., 2012). We therefore argue that stepwise screening achieves an adequate balance between reliability, acceptability and feasibility in busy clinical settings. It is also possible that the study sample may be less representative of more severely distressed and impaired substance users, since we excluded those patients with severe symptoms of dependence (defined by the SDS measure). The rationale for this exclusion was to ensure that participants were reasonably stable on medication and engaged in addiction treatment by the time they had an opportunity to take part in the study. A further consideration about the screening and recruitment method is that our pragmatic case-finding and recruitment strategy introduced a low threshold for inclusion in the study, since we set out to find participants that may not otherwise have been treatment seekers. Indeed, this low threshold meant that we had to exclude a number of patients who were screened but turned out to have primary anxiety, psychotic or bipolar disorders as illustrated in Fig. 1. We also note that nearly half of the patients that were screened but excluded from participating in the trial had either declined therapy or generally disengaged with the wider CDAT intervention.

Despite the considerable number of participants who did not engage with treatment, we managed to obtain follow-up data from 78% using a *last observation carried forward* (LOCF) method. It is of course possible that our estimations of end-point outcomes may be inaccurate since the LOCF method assumes that no change has occurred since the last available assessment. Missing follow-up data are a common limitation in clinical trials involving substance users with mental health problems (Hesse, 2009). Nevertheless, we ensured a robust analysis by applying

intention-to-treat principles and inverse probability weighting to account for missing data. A further limitation concerns the lack of formal fidelity checks over and above regular case reviews and peer supervision, which was not possible to undertake within the financial constraints of this study.

4.4. Concluding remarks

Overall, this study demonstrates that integrating stepwise mental health screening in routine addiction treatment is feasible and can be linked with cognitive and behavioral interventions, ideally co-located in the same setting to maximize engagement. As others have argued (Morisano, Babor, & Robaina, 2014; Torrens, Rossi, Martinez-Riera, Martinez-Sanvisens, & Bulbena, 2012) we take the view that system level, public health oriented, screening and psychological interventions integrated within CDAT are needed to improve the mental health and functioning of patients.

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Full length article

Brief case finding tools for anxiety disorders: Validation of GAD-7 and GAD-2 in addictions treatment

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ABSTRACT

Background: Anxiety disorders are the most common mental health problems and often co-exist with substance use. Little evidence exists to support the use of brief screening tools for anxiety disorders in routine addictions treatment. This is the first study to test the validity and reliability of GAD-7 and GAD-2 in an outpatient drugs treatment population.
Methods: A sample of 103 patients completed brief screening questionnaires and took part in structured diagnostic assessments using CIS-R. A subgroup of 60 patients completed retests after 4 weeks. The results of brief questionnaires were compared to those of gold-standard diagnostic interviews using Receiver Operating Characteristic (ROC) curves. Psychometric properties were also calculated to evaluate the validity and reliability of self-completed questionnaires.
Results: A GAD-7 score ≥9 had a sensitivity of 80% and specificity of 86% for any anxiety disorder, also displaying adequate temporal stability at repeated measurements (intra-class correlation = 0.85) and high internal consistency (Cronbach's alpha = 0.91). A GAD-2 score ≥2 had 94% sensitivity and 53% specificity, with adequate internal consistency (0.82).
Conclusions: GAD-7 adequately detected the presence of an anxiety disorder in drug and alcohol users; although this study was limited by sample size to determine its reliability for specific diagnoses. Results in this small sample suggest that GAD-7 may be a useful screening tool in addiction services, although replication in a larger sample is warranted.

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1. Introduction

Anxiety disorders are the most common among mental and brain disorders (Wittchen et al., 2011), with international prevalence rates in the region of 2.4–18.2% (WHO World Mental Health Survey Consortium, 2004). Commonly reported anxiety problems include mixed anxiety and depressive disorder, generalised anxiety disorder (GAD), panic disorder with and without agoraphobia, social anxiety, specific phobias, post traumatic stress disorder (PTSD) and obsessive compulsive disorder (OCD). These problems can range from mild presentations to very severely disabling conditions often associated with anxious apprehension, autonomic hyperarousal, intense fear and avoidance of anxiety provoking stimuli.

Questions remain about the differential classification of specific diagnoses and subtypes; however recent advances in research and clinical practice support the notion that there are key factors underlying many anxiety disorders. *Transdiagnostic* theoretical models of anxiety emphasise the central role of *negative affect* (NA: a tendency towards worry, self-criticism and negative self-view), sensitivity towards NA inducing stimuli, physiological hyperarousal and emotional avoidance strategies (Norton and Philipp, 2008). NA has also been found to play a role in the development and maintenance of problematic alcohol and drug use (Shoal et al., 2005; Mason et al., 2009). The dysregulation of stress response pathways has been well documented in alcoholism, and anxiety sensitivity is known to be implicated in chronic addictions (Kreek and Koob, 1998; Zvolensky and Leen-Feldner, 2005). Alcohol dependent subjects tend to have higher stress and adrenal sensitivity compared to healthy subjects, and it is likely that such hypersensitivity and arousal may contribute to relapse and poor treatment engagement (Sinha et al., 2011). Consistent with the 'self

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medication' theory (Khantzian, 1997), there is some evidence that people with anxiety disorders often use substances to regulate affect or avoid emotional arousal, and this ranges between 7.9% (in social phobia cases) and 35.6% (in GAD; Bolton et al., 2006). Altogether, these findings suggest that there are some common risk factors that maintain stress/anxiety states and substance use disorders. Although there is ongoing debate about the temporal sequencing and interactions between these disorders, large scale epidemiological studies suggest that anxiety disorders most often predate the onset of problematic substance use (Merikangas et al., 1998).

Unsurprisingly, people with anxiety disorders are 2–3 times at increased risk of comorbid substance misuse (Regier et al., 1990; Swendsen et al., 1998). A UK based study, for example, estimated that between 19% and 32% of patients in drug and alcohol treatment services also met diagnostic criteria for a severe anxiety disorder; however these problems often went undetected and only a minority of patients received treatment for concurrent mental disorders (Weaver et al., 2003). Such deficiencies in detection and access to targeted treatment are important, given that comorbid disorders are associated with greater rates of functional impairment and suicidality (Kessler et al., 1999).

Clinical guidelines recommend the use of standardised case finding measures to detect anxiety disorders and to monitor treatment outcomes (National Institute for Health and Clinical Excellence, 2011a). However, such measures are likely to be less accurate in substance users because intoxication and withdrawal symptoms are often similar to those of certain anxiety disorders (e.g., see alcohol withdrawal criteria in: American Psychiatric Association, 2000). Previous diagnostic validation studies have found that measures such as the Beck Anxiety Inventory (BAI) and the Brief Psychiatric Rating Scale for anxiety (BPRS-A) do not accurately distinguish between respondents with or without anxiety disorders in clinical samples with comorbid substance use (Lykke et al., 2008). The development and validation of accurate anxiety screening measures in substance users therefore remains an important area of research. This study aimed to test the validity and reliability of the 7 item questionnaire for generalised anxiety disorder (GAD-7), and an ultra-brief version of the tool (GAD-2) in a sample of outpatients in routine addictions treatment.

2. Method

2.1. Design

Brief case finding questionnaire results were compared to a gold-standard structured diagnostic interview in a cross-sectional sample of outpatients. A prospective follow-up phase of 4–6 weeks enabled us to assess temporal stability, with reference to DSM-IV criteria for differential diagnosis (American Psychiatric Association, 2000). The study was conducted as part of the CCAS programme (Case-finding and Comorbidity in Addiction Services): a wider research project investigating common mental disorders in addictions treatment.

2.2. Context and participants

The setting was a community drugs treatment service in Leeds, UK. The service offers access to medical care, structured care co-ordination and psychosocial interventions following national treatment guidelines (Department of Health, 2007). The service engages approximately 640 patients per year, many of whom have multiple social, financial and health problems. Patients commonly seek treatment for heroin, alcohol, crack and other substance dependence. Participants were recruited via sequential contacts during a full calendar year. This ensured that patients at various stages of treatment and with a range of needs had equal probability of participating. The study excluded patients with severe mental illness such as psychotic disorders identified in clinical records.

2.3. Measures

2.3.1. Generalised anxiety disorder scale (GAD-7). GAD-7 is a questionnaire initially developed to diagnose generalised anxiety disorder and to measure the severity of symptoms following DSM-IV criteria (Spitzer et al., 2006). This is a 7 item measure in which each item is rated on a 0–3 scale relating to the frequency of anxiety symptoms over the last two weeks (0 = 'not at all' to 3 = 'nearly every day'). Scores range from 0 to 21 with higher scores indicating a greater severity of anxiety. Some sample items are: "Feeling nervous, anxious or on edge?"; "Not being able to stop or control worrying?". Scores of 5, 10, and 15 are taken to represent mild, moderate, and severe levels of anxiety. This measure can be self-administered in less than 5 min, or administered by an interviewer.

The original validation study proposes that a cut-off score of 10 provides an optimal trade-off between sensitivity (89%) and specificity (82%) for a diagnosis of GAD. The measure's reliability, construct validity, and factorial validity have been established in the general population (Löwe et al., 2008). The capacity of the GAD-7 to detect other anxiety disorders including social phobia, post-traumatic stress disorder and panic disorder has also been established (Kroenke et al., 2007, 2010). A cut-off score of 8 or above has been recommended to detect cases that reliably meet criteria for any anxiety disorder. GAD-2 is an ultra-brief version of the above measure and has been recommended for use in primary care as a starting point in the detection and assessment process for anxiety disorders using a cut-off score of 3 or above (National Institute for Health and Clinical Excellence, NICE, 2011a).

2.3.2. Revised clinical interview schedule (CIS-R). CIS-R is a gold standard structured diagnostic interview that can be administered by suitably trained lay interviewers with the help of a computer interface (Lewis et al., 1992). This test generates up to 2 diagnoses based on ICD-10 criteria (World Health Organization, 1992) for non-psychotic affective and anxiety disorders including: generalised anxiety disorder, mixed anxiety and depressive disorder, depressive episode, phobias, obsessive compulsive disorder, and panic disorder. CIS-R also generates an overall severity score based on the severity rating and frequency of mental health symptoms and problems covered in the interview. A CIS-R severity score of 12 or more indicates a clinically significant diagnosis and a score above 18 is indicative of a severe disorder warranting treatment. CIS-R has been used as a diagnostic measure in the national Psychiatric Morbidity Surveys conducted in the UK (McManus et al., 2009; Meltzer et al., 1995), and also in addictions research (Gilchrist et al., 2005).

2.3.3. Secondary measures. The Severity of Dependence Scale (SDS) is a brief, 5-item measure of compulsive substance use and it covers aspects of the respondent's concern and degree of control over his or her consumption (Gossop et al., 1995). This measure has been extensively validated in adult and adolescent samples (Martin et al., 2006), with empirically derived diagnostic cut-off scores being reported for dependence to alcohol, heroin, crack, cannabis and several other illicit and prescription drugs (Lawrinson et al., 2007; Castillo et al., 2010; Kaye and Darke, 2002; Swift et al., 1998).

Drug and alcohol use was assessed using the Treatment Outcomes Profile (TOP). The TOP is a validated composite 20-item measure covering four domains: substance use, injecting risk behaviour, crime, health and social functioning (Marsden et al., 2008). This questionnaire is routinely used as an outcome measure in drugs treatment services in England as part of a drugs treatment monitoring system led by the National Treatment Agency (NTA).

2.4. Procedure

Following approval from an independent research ethics committee, patients were recruited using a standard study information leaflet. Consenting participants were invited to self-complete brief questionnaires in a confidential interview room, and staff support was provided for people who could not do so unassisted. Poor literacy was a problem for nearly a quarter of all participants, and therefore staff assistance was an important facilitator to acceptable screening (see Delgadillo et al., 2012). Participants were then asked to partake in a diagnostic interview (CIS-R) conducted by trained interviewers who were blind to self-completed questionnaire results until the end of the diagnostic interview. This was followed by an opportunity to discuss the test results and any necessary assistance or treatment. Participants were also invited to participate in a retest appointment 4–6 weeks later. Supermarket vouchers valued at £10 were offered at both baseline and follow-up appointments to incentivise participation in the study.

2.5. Data analysis

We evaluated the diagnostic accuracy of GAD-7 and GAD-2 with comparison to ICD-10 psychiatric diagnoses assessed using CIS-R as a gold standard. GAD-2 results were extracted from responses to the GAD-7 questionnaire. Brief questionnaires were evaluated as case finding tools for any anxiety disorder and also specifically for generalised anxiety disorder (GAD). Receiver Operating Characteristic (ROC) curves were used to assess the overall performance of tests with reference to the Area Under the Curve (AUC) statistic. We calculated a minimum sample of 60 cases and 43 controls to reliably conduct ROC curve analyses, according to the sampling method proposed by Flahault et al. (2005). This was based on an expected sensitivity value of 0.80 informed by the original validation of GAD-7 as a screening tool for any anxiety disorder (Kroenke et al., 2007), a minimal acceptable lower confidence limit of 0.60, and an expected prevalence rate of approximately 58% based on the figures reported by Strathdee et al. (2002) in UK substance use services. Sensitivity, specificity, predictive power and likelihood ratios were computed as indicators

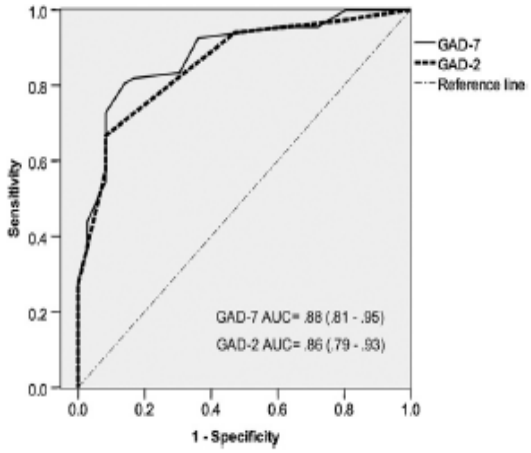

Fig. 1. ROC curves: brief case finding tools for any anxiety disorder.

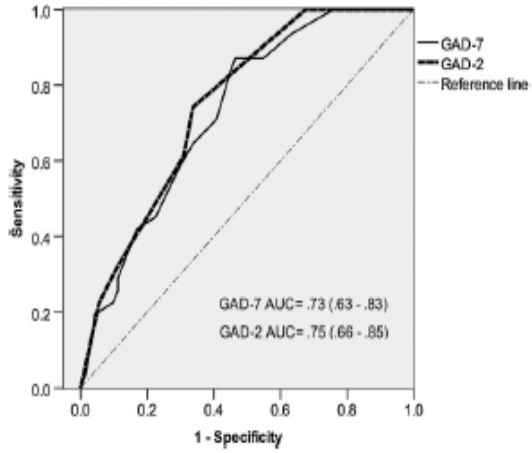

Fig. 2. ROC curves: brief case finding tools for generalised anxiety disorder.

of diagnostic validity for the optimal cutpoints identified using the ROC method. Validity was further examined by correlating the measures against the gold standard CIS-R measure (convergent validity) and the SDS which theoretically measures a distinct construct (discriminant validity). The reliability of these measures was evaluated using Cronbach's alpha to test internal consistency. Intra-class correlations were used to assess temporal stability between test and retest after 4 weeks. Finally, Youden's index was calculated as a single summary measure of overall test accuracy; where an upper index of 1 represents a perfect test, and a lower index of −1 represents a flawed test (Biggerstaff, 2000).

3. Results

We invited 162 patients to partake in the study. A total of 103 participated, 60 of whom also completed retests after 4 weeks. Only 3 patients expressly declined participation and a further 56 (35%) failed to attend their planned appointments. This was higher than the 28% attrition rate reported in outcomes research in comparable mainstream addiction services in the UK (Gossop et al., 2000). Most participants were unemployed (n = 86, 84% of total), males (n = 79, 77%) and of white British background (n = 96, 93%) with a mean age of 35 (SD = 7.09; range = 23–54). Only 5 (5%) respondents were currently in training or education. The most frequently used substances were alcohol, heroin, cannabis and crack, with 63 (61%) respondents reporting polysubstance use and only 9 (9%) reporting abstinence in the last month. More detailed demographic and clinical characteristics of the participating sample are reported in Delgadillo et al. (2011).

Sixty seven participants (65% of sample) met diagnostic criteria for an anxiety disorder according to CIS-R test results. The most commonly diagnosed anxiety disorders were GAD (n = 31, 30%), mixed anxiety and depressive disorder (n = 27, 26%), panic disorder (n = 7, 7%) and social phobia (n = 7, 7%). Comorbidity was common in this patient population; with 40 participants (39%) meeting diagnostic criteria for major depression and a secondary severe anxiety disorder (this proportion excludes mixed anxiety and depressive disorder).

Receiver operating characteristic (ROC) curves displayed in Fig. 1 summarise the diagnostic accuracy of GAD-7 and GAD-2 as screening tools for any anxiety disorder. Fig. 2 presents comparative ROC curves for the specific detection of generalised anxiety disorder. ROC curves represent the trade-off between sensitivity and specificity across the full range of values for each measure; where figures curving closest to the upper left corner are indicative of good diagnostic accuracy. A visual inspection of Figs. 1 and 2 reveals that both measures performed better as broad case finding tools for anxiety disorders rather than specifically for GAD. This was further confirmed by the comparatively higher area under the curve (AUC) values displayed in Table 1.

Table 1 describes the operating characteristics of case finding tools at different cut-off scores. A limited range of alternative cutpoints is presented for simplicity, illustrating the relative trade-off between sensitivity and specificity. We selected optimal cut-off scores which maximised specificity whilst maintaining a minimum sensitivity standard of 75%. We then calculated detailed psychometric properties based on optimal cutpoints displayed in Table 2.

GAD-7 as a case finding tool for anxiety disorders had a significant AUC value of .88 (.81–.95) and the best trade-off between sensitivity (80%) and specificity (86%) at a cutpoint of 9 points and above. GAD-2 had an AUC value of .86 (.79–.93) and was highly sensitive (94%), but its specificity was considerably lower (53%) at an optimal cutpoint of 2 and above. These results indicate that both measures are clinically useful based on conventional guidelines suggesting that AUC values ≥.70 and <.90 have moderately good

Table 1
Area under the curve, sensitivity and specificity at different cut-off scores.

	AUC (95% CI)	Cut-off	Sensitivity	Specificity
Any anxiety disorder[a]				
GAD-7	.882 (.814–.949)			
		≥7	0.833	0.694
		≥8	0.818	0.833
		≥9	0.803	0.861
		≥10	0.727	0.917
GAD-2	.858 (.785–.931)			
		≥2	0.939	0.528
		≥3	0.667	0.917
		≥4	0.576	0.917
		≥5	0.273	1.000
Generalised anxiety disorder (GAD)				
GAD-7	.730 (.631–.828)			
		≥7	0.871	0.451
		≥8	0.871	0.535
		≥9	0.839	0.549
		≥10	0.710	0.592
GAD-2	.751 (.657–.846)			
		≥2	1.000	0.324
		≥3	0.742	0.662
		≥4	0.613	0.690
		≥5	0.323	0.887

[a] Includes: GAD, mixed anxiety and depressive disorder, panic disorder, agoraphobia, social phobia, specific phobias, obsessive compulsive disorder.

Table 2
Psychometric properties of anxiety disorder screening tools at the optimal cut-off scores.

	Cronbach's α	ICC	Cut-off	Sensitivity	Specificity	+PV	−PV	+LR	−LR	Youden's index
Any anxiety disorder[a]										
GAD-7	0.914	0.854	≥9	0.803	0.861	0.914	0.689	5.696	0.243	0.652
GAD-2	0.820	0.811	≥2	0.939	0.528	0.785	0.826	1.989	0.115	0.467
Generalised anxiety disorder										
GAD-7	0.914	0.854	≥9	0.839	0.549	0.448	0.889	1.887	0.290	0.394
GAD-2	0.820	0.811	≥3	0.742	0.662	0.489	0.855	2.195	0.390	0.404

ICC, intra-class correlation; PV, predictive value; LR, likelihood ratio.
[a] Includes: GAD, mixed anxiety and depressive disorder, panic disorder, agoraphobia, social phobia, specific phobias, obsessive compulsive disorder.

accuracy and AUC values ≥.90 are highly accurate (Swets, 1988; Greiner et al., 2001). GAD-7 was accurate in 91% of cases with a positive screen and 69% of cases that did not screen positive. The corresponding positive and negative predictive values for GAD-2 were 78% and 83% respectively. Although GAD-7 was most accurate overall, it was more accurate in confirming cases (+PV = 0.91) whilst the GAD-2 measure was more accurate in confirming non-cases (−PV = 0.83). Positive and negative likelihood ratios (LR) are also displayed in Table 2. These indicated that patients with an anxiety disorder were 5.7 times more likely than patients without an anxiety disorder to have a GAD-7 score of 9 or greater. A negative LR of 0.24 indicated that patients with an anxiety disorder were only one-fourth as likely as a person without an anxiety disorder to have a GAD-7 score less than 9. Table 1 additionally presents comparative psychometric properties for GAD-7 and GAD-2 as case finding tools for generalised anxiety disorder.

GAD-7 had robust internal consistency indicated by a Cronbach's alpha value ($\alpha = .91$) above the conventional threshold of .70 (Nunnally, 1970). Temporal stability of anxiety symptoms measured by GAD-7 was highly consistent when correlating baseline and retests after 4–6 weeks (ICC = .85), taking a conventional threshold of >80 to indicate substantial agreement between measures (Shrout, 1998). The shorter version of the scale displayed a Cronbach's alpha value of .82 and comparable temporal stability (ICC = .81). There was a significant correlation between GAD-7 and CIS-R ($r = .76$, $p < .001$), indicating strong convergent validity. GAD-7 was also significantly correlated to SDS ($r = .39$, $p < .001$), although the coefficient value suggests a weak association, indicative of good discriminant validity. The same pattern was observed for GAD-2 when correlated to CIS-R ($r = .73$, $p < .001$) and SDS ($r = .25$, $p = .01$).

4. Discussion

4.1. Main findings

The present results support the use of GAD-7 as a measure with adequate internal consistency and diagnostic accuracy for the detection of anxiety disorders. Our correlational analyses also indicate that the GAD-7 has strong criterion validity and acceptable discriminant validity. The ultra-brief version had generally comparable performance indicators, although its specificity tended to be lower than that of the 7 item measure. Nevertheless, the post-test probability of anxiety disorder was above 78% for a positive screen on either measure, suggesting that both are clinically useful. Anxiety symptoms were temporally stable, as demonstrated by the moderate agreement between baseline and follow-up measurements after a period of 4 weeks. This follow-up period of at least a month observation of symptoms is concordant with guidelines for differential diagnosis (APA, 2000).

The performance of the full and abridged measures was less impressive when screening for generalised anxiety disorder. The very high prevalence of other comorbid anxiety disorders in this population had an impact on the measure's specificity or ability to adequately discriminate respondents who did not meet criteria for GAD. The 2 core items of the measure tended to be relevant to a range of anxiety presentations and therefore GAD-2 was less suitable for use as a specific case finding tool for GAD in this population. However, it is acknowledged that this study sample was underpowered to robustly evaluate the diagnostic accuracy of brief screening tools for GAD or other specific diagnoses, so these results require further validation in a larger sample.

4.2. Limitations

Our recruitment method involved the use of incentives and opportunistic recruitment in an outpatient clinic. This recruitment method may have possibly excluded some patients with more complex needs; for example those who require home visits and assertive engagement outside of clinic. Nevertheless, demographics, clinical factors and drug use patterns in this sample were generally comparable to trends reported in UK drug treatment outcomes research (Gossop et al., 1997). We argue that our recruitment strategy enabled the inclusion of a representative sample of patients in mainstream UK community drugs treatment, which adds weight to the generalisability of our results.

An important limitation was the relatively small sample size in this study. Although the recruited sample was adequate to evaluate the diagnostic accuracy of brief case finding tools for any anxiety disorder, the sample was far too small to reliably conduct psychometric testing for specific anxiety disorders which had smaller prevalence rates. Therefore the brief measures' performance with regards to generalized anxiety disorder should be taken as a preliminary result which warrants further validation in a larger sample.

Unlike some diagnostic interviews such as PRISM (Hasin et al., 1998), CIS-R does not probe for the temporal sequencing of substance use and other axis I disorders, or the pervasiveness of psychological symptoms in periods of abstinence from alcohol or drugs. Such methods are often advocated to detect drug induced mental disorders (Schuckit et al., 1997; Schuckit, 2006). Whilst we acknowledge this limitation, previous research using the PRISM interview demonstrated that drug-induced anxiety and affective disorders are fairly uncommon compared to induced psychotic symptoms (Torrens et al., 2011). We therefore argue that the potential false positive rate that may be related to our choice of diagnostic interview is at worst modest, and at best compensated for by our efforts to evaluate re-test reliability after a 4 week period.

4.3. Clinical and research implications

Clinical guidelines for the detection and treatment of anxiety disorders such as GAD and panic disorder alert practitioners to the common occurrence of comorbid substance misuse (NICE, 2011b, pp. 26–27). However, the accurate identification of clinically significant anxiety disorders in the presence of dependent

substance use is an important problem. The acute symptoms of intoxication or withdrawal often mimic those of anxiety disorders, but can be of a transient nature and subside after the discontinuation of alcohol or drug use (Schuckit, 2006). Stress associated with the acute phase of a substance use disorder and access to treatment can also account for elevated anxiety and depressive symptoms (Elbogen et al., 2005). This quandary is accentuated by a general dearth of skills in the detection of diagnosable mental health problems in mainstream addictions treatment services (Weaver et al., 2003).

The use of valid and reliable case finding measures for anxiety disorders is therefore a potentially useful clinical strategy within a context of high prevalence and disability. Previous studies have set out to validate anxiety measures in clinical samples with substance use. McPherson and Martin (2011) reviewed studies on the Hospital Anxiety and Depression Scale (HADS) and concluded that it had a suitable factor structure, adequate internal consistency and re-test reliability. However, this review did not find any specific primary studies that had investigated the psychometric properties of HADS in homogeneous samples of alcohol users. As described in the introduction, other anxiety measures evaluated in patients with comorbid substance use disorders did not reliably detect anxiety disorders (Lykke et al., 2008). Our study expands the evidence base for the validity and reliability of anxiety measures in routine addictions treatment. GAD-7 has several advantages such as the brevity of the scale, its flexible use as a self-completed or clinician-administered questionnaire, and the acceptable reliability of its core 2 items (GAD-2). Furthermore, GAD-7 is increasingly becoming a widely used measure in primary care given its brevity, the availability of translated versions in several languages and its availability in the public domain which makes it more appealing compared to other proprietary measures. For example it is used in routine psychological therapy services working under the national IAPT (Improving Access to Psychological Therapies) programme in England as a routine screening tool and outcome measure (National IAPT Programme Team, 2011).

Implementation and use of routine screening strategies, however, should not solely rely on evidence of diagnostic accuracy. There is still limited evidence of improved outcomes or treatment take-up following screening (Gilbody et al., 2001; Gilchrist and Gunn, 2007). Robust clinical trial data is required to confidently advocate the routine implementation of screening strategies in tandem with evidence based treatments for comorbid depression and anxiety in addictions treatment. Emerging literature in the field demonstrate that anxiety disorders can be effectively treated in primary care (Rollman et al., 2005; Roy-Byrne et al., 2010). Such systems-based interventions coupled with screening should also be tested in patients with substance disorders.

Future validation studies in larger samples using interviews such as PRISM would strengthen the evidence base for the reliability and utility of anxiety case finding tools; particularly with more hard-to-engage groups such as those affected by homelessness, those in criminal justice services and harm reduction services. In addition, the validation of self-completed measures for specific anxiety disorders in addictions treatment may help to increase the precision of case finding strategies in this population with multiple comorbidities. Given the challenges of conducting research and recruiting participants in this patient population, further multi-site studies are encouraged to maximise sample size and generalisability of results.

In conclusion, the present study results support the use of GAD-7 as a case finding measure for anxiety disorders in routine drugs treatment services. Its brevity and ease of use makes it a potentially helpful tool to identify those patients with comorbid disorders who may benefit from integrated treatment for substance misuse and anxiety problems.

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Contributors

All authors designed the study and wrote the protocol. Author JD undertook the statistical analysis in consultation with author VD. Author JD wrote the first draft of the manuscript. All authors contributed to and have approved the final manuscript.

Conflict of interest

All authors declare that they have no conflicts of interest in the conduct of this research.

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Acceptability of mental health screening in routine addictions treatment

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Abstract

Objective: The objective was to investigate patients' views on the application of case finding and screening methods for common mental disorders in an addiction treatment service.
Method: Qualitative thematic analysis of semistructured interviews with a purposive sample of 19 participants. Participants took part in diagnostic assessments (Revised Clinical Interview Schedule, CIS-R) and completed brief screening questionnaires for depression (Patient Health Questionnaire, PHQ-9) and anxiety (Generalized Anxiety Disorder Scale, GAD-7).
Results: Patients generally favored the use of screening questionnaires to detect psychological problems, to monitor changes in symptoms and to facilitate targeted and specialist treatment. On the whole, respondents seemed to find such methods familiar and easy to use. The need for staff support was strongly emphasized, both to deal with the emotional impact of screening and to overcome accessibility and literacy problems. Good therapeutic rapport with practitioners came across as an important factor that influences patients' willingness to discuss psychological problems. Patient readiness and the timeliness of assessments were additional factors influencing acceptability. Participants discussed how psychological problems and substance misuse are associated in complex ways, often resulting in discrimination, poor recognition of such problems and limited access to treatment.
Conclusions: Mental health screening is generally acceptable to patients and can help to identify comorbid mental disorders in order to provide appropriate support and treatment.
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Keywords: Screening; Depression; Anxiety; Addiction; Acceptability

1. Introduction

Depression and anxiety disorders are highly prevalent in addiction treatment services [1–3], yet their detection and assessment are often inconsistent in routine practice [4]. Although UK policy developments in the last decade have advocated improving the assessment and treatment of comorbid psychiatric disorders [5], little is known about patients' perspectives on the acceptability and use of mental health screening methods.

When considering the value of screening strategies, most published research has focused on diagnostic utility, sensitivity and specificity. Remarkably few studies shed light on patients' experiences and views on the matter. This is important because one of the core attributes of any screening approach is that instruments and tests should be acceptable to patients [6]. Qualitative evidence of patient perspectives on mental health screening has been mostly advanced in the area of postnatal depression (PND). In a systematic review of qualitative studies in PND, Brealey et al. [7] emphasize the importance of confidentiality, advance

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warning and preparation for screening. They also note that a trusting therapeutic relationship with healthcare providers is a key facilitator to the acceptable implementation of screening. Only a handful of acceptability studies in other areas of healthcare have been published with relation to mental health screening [8–10]. These studies generally support routine screening and suggest a reasonable degree of convergence between questionnaire results and in-depth patient interviews about their experiences of depression. Common criticisms to questionnaire-driven screening include scepticism about the accuracy of results, interference with therapeutic rapport and lack of direct connection between screening and treatment.

Questions remain about the adequacy of mental health screening with drug-dependent patients who typically present high psychiatric morbidity rates [11] and are at increased risk of treatment disengagement [12] and adverse outcomes such as homelessness, criminality and suicide [13]. The aim of this study was to investigate the acceptability of mental health screening in the context of alcohol and drug addiction treatment. This paper presents an in-depth exploration of patients' experiences and views of alternative mental health case finding methods and proposes some general implications for clinical practice.

2. Methods

2.1. Design

This was a qualitative study based on a thematic analysis of semistructured interviews.

2.2. Context

The study was conducted as part of the Case-finding and Comorbidity in Addictions Services (CCAS) program, a research project investigating the reliability and validity of brief screening tools for depression and anxiety in a community drugs treatment service in Leeds, UK. The service offered access to medical care, structured care coordination and psychosocial interventions following national treatment guidelines [14]. The majority of participants were opioid-dependent individuals on agonist treatment.

2.3. Theoretical frame

Broadly grounded in the critical realism paradigm [15,16], our explicit theoretical assumptions were the following. There is an objective reality that exists independently of our knowledge of it, and we can learn about this through careful observation and interpretation within the context in which the phenomenon occurs. Because knowledge of reality is apprehended through the observer's subjective reference frame, rigorous efforts must be made to guarantee confidence in the observer's interpretation. *Validity* of produced knowledge, hence, does not refer to an absolute and certain reflection of reality, but rather one with a reasonable degree of credibility and intersubjective agreement [17]. Several methods exist to pursue a valid and rigorous production of knowledge including careful purposive sampling, negative case analysis, reflexivity and peer review [18].

2.4. Sampling and recruitment

The participants in this study were recruited from a wider sample of patients taking part in a diagnostic evaluation of brief screening tools. Inclusion criteria were wide and targeted all patients accessing routine treatment with or without common mental disorders, only excluding those with known severe mental disorders (such as psychosis or bipolar affective disorder) given our focus on depression and anxiety.

The qualitative study used an a priori stratified and purposive sampling strategy based on two factors: gender and diagnostic status. We chose this strategy as a means of introducing variation in our sample guided by existing literature in the field. Gender differences have been proposed with regards to readiness to disclose psychological distress to others and readiness to seek social support [19]. We also considered differences in diagnostic status to be important, consistent with research showing some differential attitudes towards mental health and support seeking according to depression status in community samples [20].

Following approval from an independent research governance and ethics committee, consenting participants were invited to complete self-reported screening questionnaires for depression (Patient Health Questionnaire, PHQ-9) [21] and anxiety (Generalized Anxiety Disorder Scale, GAD-7) [22,23], immediately followed by a structured diagnostic assessment. Diagnostic interviews were conducted by case managers trained to use the computer-based version of the Revised Clinical Interview Schedule (CIS-R) [24]. Case managers provided feedback about the diagnostic results immediately, using a detailed symptom report produced by CIS-R. Participants were offered ample time to discuss any concerns or questions with clinical staff and to consider support and treatment options. Informed consent was then sought again to partake in qualitative interviews within a period of 2 weeks. Recruitment proceeded in this manner until an equitable number of consenting participants matched the predetermined sampling frame described above. A total of 23 participants were approached, out of whom 19 consented and took part in qualitative interviews during a study period of 1 year. This was 18% of the total sample for the wider CCAS program (n=103). Participation in the study was incentivized by the provision of £10 supermarket vouchers, in line with the recommendations of research in the field [25] and service user involvement policy developments [26].

2.5. Data collection

Confidential telephone interviews were conducted by an independent researcher (P.S.) who had no clinical role within the service, providing a degree of anonymity and impartiality. Interviews followed a semistructured questionnaire informed

by the topic guide developed by Dowrick et al. [8]. The guide was modified to match the explicit objectives of this study by our research team whose areas of expertise are psychiatry, psychiatric nursing and psychological therapy. A condensed outline of the topics covered is presented in Table 1. Interviews followed the topic guide closely enough to ensure consistency across participants, using predetermined prompts as necessary. All interviews were audio recorded and transcribed verbatim.

2.6. Data analysis

Our analytical strategy followed the six stages of thematic analysis described by Braun and Clarke [27]. Stage 1 involved familiarization with all data and initial note taking. Stage 2 focused on 'open coding' of data through a line-by-line inspection of transcripts. Thirdly, we clustered codes into potential themes through constant comparison within and across transcripts. The fourth stage involved generating a thematic map and checking compatibility with individually coded extracts across the data set. The fifth stage involved refining themes into a coherent narrative structure. Finally, we selected data extracts to produce a descriptive and theoretical argument consistent with the purpose of the study.

In the interest of analytical reliability and reflexivity, researchers were divided into two pairs (J.D. with D.J., S. Gore with S.P.) who separately performed *open* and *axial* coding (stages 1, 2 and 3). This enabled a robust identification of prominent themes identified by both sets of researchers, as well as the detection of conflicting evidence or negative cases and idiosyncratic meanings and perspectives inevitably introduced by the researchers themselves. Stages 4, 5 and 6 involved all researchers in iterative data analysis meetings aiming to develop and refine a thematic narrative accounting for all data and accommodating negative cases. Further validation of our analysis was sought by seeking feedback from the interviewer who collected the raw data (P.S.). Analysis was assisted by the use of QSR NVivo software for node and tree mapping of coded data transcripts [28] and Microsoft Excel to perform clustering of themes and matrix analysis [29].

Table 1
Topic guide summary

Topic	Description
1	Preferences between brief self-completed questionnaires vs. structured diagnostic interviews
2	Experience of going through a mental health assessment
3	Emotional impact of the experience
4	Perceived difficulties and facilitating factors for the completion of questionnaires
5	Understanding of the purpose of mental health screening
6	Understanding of the scoring procedure and interpretation of questionnaire results
7	Views about the management of mental health problems in addictions treatment
8	Views about the utility of screening methods
9	Views about implementation of screening methods in routine practice
10	Any other views or opinions following the participant's agenda

Table 2
Sample characteristics

Characteristic	n	%
Demographics		
Female	9	47
Male	10	53
White British	19	100
Mean age (range)	35 (25–52)	
Unemployed	18	95
In training or education	1	5
Acute housing problem	2	10
Psychiatric diagnosis		
No current mental disorder	9	47
Mixed depressive and anxiety disorder	7	37
Major depression	1	5
Mild depressive episode	1	5
Specific phobia	1	5
Substances used in the last month		
Alcohol	11	58
Heroin	9	47
Cannabis	9	47
Crack	5	26
Amphetamines	1	5
Polysubstance use	12	63
Injecting	5	26
Frequency of use (for any substances used in the last month)		
Abstinent	4	21
Using 1–2 times per week	6	32
Using 3–4 times per week	3	16
Using 5–7 times per week	6	32
Treatment		
Substitute opiate prescription	18	95
Antidepressants	6	32
Mean no. weeks in treatment (range)	105 (1–249)	

3. Results

Table 2 presents a summary of relevant participant characteristics. Rates of substance use were generally comparable to the wider CCAS sample [30], although the rate of abstainers in this study group (21%) was twice that of the wider sample (9%). This study group also differed with respect to gender and psychiatric diagnosis, consistent with our purposive sampling strategy that aimed to attain an equal distribution in these factors. The prevalence of psychiatric disorders in the wider CCAS sample was 70%, and most participants were males (77%).

We present our interpretative analysis organized according to five general themes, along with supporting data extracts linked to participant codes [1].

[1] Participant codes are used to convey respondents' gender and diagnostic status without compromising confidentiality. M=male; F=female; P=positive psychiatric diagnosis; N=negative or no psychiatric diagnosis. Numbers denote: transcript number, line number.

3.1. Theme 1: Experience of different mental health screening methods

Participants were asked to comment on their experiences of the structured diagnostic interviews (CIS-R) and paper-based mental health questionnaires (MHQs), noting any preferences between them. Overall, no clear preferences towards either of the case finding methods were strongly found in our analysis, with most participants expressing indifference: "I don't think I had a preference really" (MP1, 114); "it were the same really, it was as fast as each other so I wasn't bothered" (FN19, 72).

Some participants associated the paper-based MHQ with three strengths: ease of use, time taken to complete and familiarity: "Pretty straightforward, pretty easy really" (MP5, 143); "better because it were quicker" (FP18, 99); "I've done a lot of paper based questionnaire surveys [...] and I'm pretty good with questionnaires" (FN7, 131). However, a number of weaknesses were identified, including lack of depth and failure to capture participants' experience: "It should have been more in depth and a bit longer, you know a few more questions" (MP1, 196). Other patients commented on the imprecise multiple-choice options in the MHQ Likert scales ranging from 0 to 3: "Some of them it was difficult because you might be kind of in between, [...] so I put the nearest that applied to me" (FP2, 225). For those participants who preferred the structured diagnostic interviews, the focus of opinion centered on how the CIS-R explored mental health symptoms in greater depth: "It seemed to go a bit deeper" (FP9, 63).

Common criticisms to both case finding methods were noted with regards to accessibility for people with poor literacy skills. Some participants indicated that staff support and ample opportunity for discussion are necessary in the context of mental health screening: "I understood it a bit better with the, you know, when it was somebody helping me" (FN4, 115).

3.2. Theme 2: Understanding of the purpose and interpretation of screening tests

We were interested in exploring what the interviewees had understood about the purpose of the questionnaires and how results were interpreted and used. Most participants were aware that MHQs were used for the detection of depression and anxiety specifically, and even whether suicidal thoughts were present: "To find out if you suffer from depression or whatever else" (MN17, 102); "it were about depression and anxiety, suicide" (FN4, 137). Many were also able to discuss what the score on the MHQ represented, for example, how severe their condition was or if they had a specific diagnosis or not: "It's just like how depressed you are I think, or the level of anxiety you're suffering" (MP1, 373). A small number of respondents could only offer fairly vague explanations due to poor recall: "I can't remember, erm, is it about your feelings?" (MN14, 193). Others merely alluded to research purposes as the main rationale for using the tests: "To find out if one [*screening method*] works better than the other" (MP1, 211).

Some participants clearly analyzed the use of these questionnaires at a more complex level, for example, elaborating on how screening tools could be used to differentiate between mental disorders and 'stress,' between primary and drug-induced symptoms, or even to tell if someone was feigning symptoms: "They can pick up on whether someone's telling the truth about how depressed they are, if they are depressed or full of anxiety or whatever [...] and the differences between anxiety and depression and stress" (MP1, 426); "They use them to see if there's a connection, you know, between people that use or have used drugs and mental health issues" (FP2, 301).

3.3. Theme 3: Emotional responses to case finding and screening for mental health problems

Some respondents indicated that they felt relatively at ease in discussing their mental health: "I discuss them [*mental health problems*] when I go see my workers anyway so it doesn't bother me really" (FP2, 214). Hence, some participants more familiar with the subject expressed either apathy or tedium: "I didn't find out much more than what I already know" (MN17, 176); "It was going on and on a bit" (FN12, 302).

For some participants, gaining further understanding of their mental health seemed to generate a positive emotional response: "I was talking to one of the workers in there and like I had problems with concentrating and I never knew it had ought to do with depression, and I found out that was why. [...] I understood a lot more what was happening to me than before" (FP13, 176). Some had recently been diagnosed as part of their routine health care and found it a positive experience to be able to learn more about what this meant, even suggesting that this insight would help with their treatment: "I was quite interested because I've just recently been diagnosed, so I were as honest as I could be with the answers" (FP6, 142); "it gave me something to think about which also helped, you know, like with the treatment I'm going to get, with the counselling as well. [...] At the end you can get a print out, erm, of symptoms. It gives you scores, well mine was quite high. I said look can I have a copy of that, to look at things in it and to use some of this to help" (MP11, 86). The assessment and screening process also led some participants to get a sense of acknowledgement of their emotional and personal difficulties: "It was better because of people taking an interest in it. It was actually like they were bothered about what you're feeling" (MN15, 86).

A smaller number of participants found it uncomfortable to talk about their mental health and even suggested that others may find it offensive: "It [*screening*] just felt intrusive" (MP5, 184); "some people might find it offensive [*to be asked about their mental health*]" (FN4, 298). Some participants were surprised about their diagnostic results, leading to reactions of upset and scepticism: "It was the

result what upset me. I don't think it was right" (MP1, 141); "I was surprised because when my result came out, er, it said that I was depressed but at the moment I don't feel depressed" (FP9, 333). Others noted a concern that screening could have a negative effect on some patients, potentially raising problematic issues and having an impact on drug use: "You might have somebody who just doesn't deal with something that's just come out, like something that's just struck a nerve, then they go out and make things worse for themselves" (MP11, 360).

3.4. Theme 4: General views on mental health and treatment

There was an understanding that there is a high prevalence of common mental health problems in this population and that these issues are not always recognized by services or disclosed by individuals themselves: "Because you know at end of day there's a lot of people with mental health problems [...] even the people that we don't know about" (FN4, 286).

Several individuals discussed their views about the association between drug use and mental health problems: "Depression is usually one of the reasons that you get into it [*drug use*], and if it's not why you have got into it, you'll end up depressed by the end of it" (FP6, 265); "I mean I can't speak for other people but for myself, right, when times I have been a little low and depressed that's mainly when I have used" (FP13, 169). One participant strongly felt that people who suffered with this combination of problems were often discriminated against, and hence their access to treatment was limited: "You know that they shouldn't be discriminated against" (FP2, 337).

Many respondents also highlighted a need for improved assessment and treatment. Suggestions included the provision of enhanced psychological treatment within the addictions service: "Diagnosing it [*depression*] and getting treatment is the key issue in getting off drugs, and helping you stay drug free" (FP6, 268); "Drug taking is all about your moods and obviously if you're struggling then you're having bad days. If they know about it, I suppose they can help you address it" (FP13, 191). Furthermore, the need to use screening results to refer to specialist services depending on the nature of the patient's particular problems was emphasized strongly: "You know, there's no good sending someone to a bereavement counsellor when they've been raped. It's no good sending someone to a rape counsellor if they've lost a baby, you know. So you need to find out these things and help with whatever the person is feeling" (FN7, 251).

3.5. Theme 5: Views on the implementation of case finding and screening

Participants were asked to share their views about whether or not addiction services should use mental health screening strategies and how this might work in practice.

Some respondents suggested that screening should be done routinely, at the beginning of a course of treatment, and could be used repeatedly to assess changes: "Use it [*MHQ*] for part of my treatment, and then you could chart your progress with that. I think you could coincide that with a session, you know therapy, as part of your treatment ongoing. Like this is where you were, and look where you are now" (MP11, 309); "We'd see the difference in ourselves one way or another, you know, having to do it again, you know six months down the line, having to do it again or twelve months or whatever" (MP1, 480).

Other respondents were more cautious and suggested that screening should take place depending on patients' readiness to address mental health issues as part of treatment. The notion of therapeutic alliance became an integral part of several responses, in which participants suggested differing levels of willingness to discuss mental health at different times in their treatment: "I think it should be down to the individual [*the timing of mental health screening*]. It took me quite a long time to ask for help" (MP10, 249); "I think with some cases it might be a good idea to leave it a few weeks, I suppose it's, erm, down to you lot to sort of judge the character of the person as you're getting to know them." (FN7, 329); "If you feel more comfortable you give a more truthful answer, developing trust" (MP5, 361).

The importance of the therapeutic alliance was highlighted by reflections on completing the MHQ with the support of a member of staff, which was expressed as preferable to self-completion of questionnaires: "The fact that I was with somebody who could offer support, because afterwards she didn't just bugger off, she stayed with me for a while and we talked about things" (MP11, 102). Some respondents emphasized their expectations that services should have staff with expertise in mental health: "I can talk to the drug service okay, it's just I think it would be easier to talk to somebody who's actually in that line of business, you know with mental health. A drug counsellor is basically just there to work with your drug problem. Unless they have actually trained in mental health" (MP10, 197).

Most participants considered that the introduction of routine screening could help to improve the detection of mental disorders and to facilitate more appropriate and targeted help for such problems: "They're obviously not diagnosing people good enough at the minute, so they're taking measures in being able to do that" (FP6, 242); "I think a lot of people don't recognise mental health issues as being er, you know, as being a problem to people. [...] There could be a little more help around for people that have issues like that" (FP2, 331).

4. Discussion

In this study, we considered the acceptability and feasibility of employing structured case finding strategies for common mental health problems in routine addiction treatment from the perspective of patients. Our findings

generally indicate favorable views on the utility of questionnaires to detect psychological problems, to monitor changes and to facilitate targeted treatment. Most respondents seemed to find such methods familiar and easy to use. Some limitations were noted regarding technical language and imprecise matching between questionnaire items and some patient experiences. The need for staff support was strongly emphasized to deal with the emotional impact of screening and to overcome accessibility and literacy problems. Good therapeutic alliance with practitioners came across as an important factor that influences patients' willingness to discuss psychological problems. Patient readiness and timeliness of assessments were suggested as additional factors which should be considered when deciding to apply screening strategies in individual cases. Participants discussed how psychological problems and substance use are associated in complex ways, often resulting in discrimination, poor recognition of such problems and limited access to treatment.

4.1. Reflexivity considerations

This qualitative study was conducted within a wider validation of brief screening questionnaires. In this context, considerable effort was made to train and to involve addiction treatment staff in research, raising awareness of mental health problems over a sustained period. These efforts may have vicariously influenced participants' attitudes and views on the utility of screening. It is possible that screening in other services with less enthusiasm for or expertise in mental health may influence patients' experiences differently. Furthermore, we acknowledge that the use of monetary incentives (vouchers) to maximize research recruitment artificially influences demand and acceptability of screening in ways that may not be reflective of routine treatment where such incentives are absent.

Our methodological choices and analytical strategy were partly driven by funding and time pressures, which inevitably come with practice-based research. For example, funding constraints led us to decide to use purposive sampling with a maximum number of 20 participants, using a topic guide constructed a priori, rather than following a theoretical sampling strategy seeking data saturation. This strategy inevitably influenced the type of responses and information collected, which may have varied by using other analytical approaches such as traditional grounded theory.

As a research team comprised by full-time clinicians, we were particularly mindful of mental health as an area in need of development and investment. Hence, we took a pragmatic approach to research, formulating a topic guide focused on identifying key problems and solutions rather than focusing on theoretical and philosophical considerations. This inclination to pragmatic critical realism led us closer to thematic analysis rather than other methods with greater emphasis on the generation of theory.

4.2. Research, policy and practice implications

Against a backdrop of limited qualitative research in this area, our findings generally converge with several key themes highlighted in the postnatal depression field [7], notably in what concerns the importance of preparation for screening, the timing of tests and the prominence of the therapeutic relationship. Consistent with Dowrick et al. [8], our findings suggest that patients consider the use of such measures acceptable, and many find that screening indicates that their problems are being acknowledged and taken seriously by professionals. The importance of rapport and sensitive interpersonal discussion in the context of mental health screening described above also converges with the findings in Leydon et al. [31].

It should be noted that the sample in this study was comprised largely of polysubstance users who were being treated with substitute opiate agonists for opioid dependence, and therefore, the results presented in this report should be read as reflective of a mainstream drug treatment center in the UK. It may be that our sample results do not necessarily reflect the acceptability of screening methods in the wider addiction treatment population. Nevertheless, this study presents important implications for policy and clinical practice. In a quantitative arm of the CCAS research program, we have empirically tested and demonstrated the reliability of brief depression screening tools in community drugs treatment [30]. The present findings provide further support for the use of such measures in routine practice; however, several important factors should be considered in the context of implementation.

Patients in routine drugs treatment commonly go through extensive and repeated assessments; for this reason, consideration of the length of mental health interviews and case finding tools is very important to minimize the burden of assessment and to enhance acceptability. Brief tools can also be embedded in electronic patient records which may facilitate their use by clinicians. In both these senses, brief case finding tools may offer advantages over in-depth diagnostic interviews.

The UK National Screening Committee has produced extensive guidelines for the appraisal of screening programs, drawing attention to safety, acceptability, cost-effectiveness and clear links to treatment among other key considerations [32]. In line with such recommendations, we propose that routine case finding and screening should be supported by robust training and professional development initiatives to ensure adequate competence in mental health. Recent studies demonstrate that structured training for non-mental-health specialists can significantly improve detection and treatment rates for patients with common mental disorders [33]. Furthermore, there is some emerging evidence of the effectiveness of low-intensity treatments for substance users with common mental disorders [34,35], which may be feasible to integrate within drugs treatment settings. Adequate pathways into psychiatric and specialist psychological

treatment should also be considered before broad implementation of screening, particularly for patients with more complex and severe disorders. This might be achieved through fostering collaborative care networks via locally driven and multidisciplinary practitioner groups or through the integration of specialist mental health professionals into community drugs services. Although the literature in the field has thus far not favored either collaborative or integrated treatment models [36], our findings suggest that the availability of staff with expertise in mental health is a key facilitator to therapeutic rapport, disclosure and willingness to access support.

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Research report

How reliable is depression screening in alcohol and drug users? A validation of brief and ultra-brief questionnaires

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ABSTRACT

Background: Depression is highly comorbid with alcohol and drug problems, resulting in greater impairment, reduced treatment adherence and poor outcomes. Little evidence exists to support the use of mental health screening tools in routine addiction treatment. This study tested the validity and reliability of PHQ-9 and PHQ-2 as depression case finding tools in an outpatient drug treatment sample in the United Kingdom.

Methods: A sample of 103 patients took part in diagnostic assessments using CIS-R and completed brief screening questionnaires. A subgroup of 60 patients completed retests after 4 weeks. Diagnostic results were compared to brief measures using receiver operating characteristic (ROC) curves. Psychometric properties were also calculated to evaluate the validity and reliability of self-completed questionnaires.

Results: A PHQ-9 score ≥ 12 had a sensitivity of 81% and specificity of 75% for major depression, also displaying good retest reliability (intra-class correlation, 0.78) and internal consistency (Cronbach's alpha, 0.84). PHQ-2 had 68% sensitivity and 70% specificity, with more modest retest reliability (0.66) and internal consistency (0.64).

Limitations: Diagnostic interviews did not consider the temporal sequencing of the onset of drug use and mental health problems.

Conclusions: PHQ-9 is a valid and reliable depression screening tool for drug and alcohol users. The brevity and ease of administration of self-completed questionnaires make them useful clinical tools in addiction services commonly encountering a high prevalence of depression.

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1. Introduction

Depression is a major cause of disability, lost productivity, social impairment and excess mortality by its deleterious effect on other chronic health problems and by increased risk of suicide (National Institute for Health and Clinical Excellence, 2010). Depression is also known to commonly co-exist with alcohol and drug addictions, often resulting in greater functional impairment (Johnson et al., 1995), reduced treatment adherence (Carroll et al., 1993; Ford et al., 1991) and poor health outcomes (Hasin et al., 2002; McKay et al., 2002). The disproportionate prevalence of this comorbidity pattern in addiction treatment settings has been underlined by several epidemiological studies (Schifano, 2002; Strathdee et al., 2002; Weaver et al., 2003). The COSMIC study conducted in the UK, for example, reported that at least 60% of patients in routine drug treatment had a depressive disorder (Weaver et al., 2003).

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In contrast, the national point prevalence estimates in working age adults are 2.6% for depression and 11.4% for mixed depression and anxiety (Singleton et al., 2001). In recent years evidence has emerged relating to the implementation of screening, outcome measurement and interventions for depression in primary care (Gilbody et al., 2005; Henkel et al., 2004; Hickie et al., 2002; Löwe et al., 2004; NICE, 2010; Palmer and Coyne, 2003; Sharp and Lipsky, 2002). These efforts have yet to be mirrored in the addiction treatment field.

Although there is some evidence for the treatment of depression in drug users (Lingford-Hughes et al., 2004; McIntosh and Ritson, 2001; Nunes and Levin, 2004; Nunes et al., 2004), there is a dearth of research on the reliability of case finding strategies to adequately detect patients who may benefit from such treatment. Earlier studies have tended to show poor specificity and modest predictive power of brief screening tools such as Beck Depression Inventory, Hamilton Depression Scale, Symptom Checklist 90, Addiction Severity Index-psychiatric problems scale and other measures commonly used in addictions research (Franken and Hendriks, 2001; Hesselbrock et al., 1983; Rounsaville et al., 1979; Weiss, et al., 1989; Willenbring, 1986).

A few studies investigating a new generation of screening tools have reported more promising reliability indices; however, questions remain about the confidence with which such measures can be applied in mainstream services. Zimmerman et al. (2004), for example, tested the reliability of the Psychiatric Diagnostic Screening Questionnaire (PDSQ) in a large sample of psychiatric outpatients with and without substance use disorders. They reported mean sensitivity and specificity values of 92% and 63% for respondents with substance use disorders (96% and 64% for the depression subscale), compared to corresponding mean values of 88% and 64% for respondents without addiction problems. However, the applicability of such a measure in mainstream services without further validation is fraught by questions of generalisability and feasibility: First, the above study was conducted in a private fee-paying clinic in the United States; therefore demographic characteristics such as education, employment, social support and age are very likely to differ to those in UK primary care settings. Secondly, the length of the PDSQ (126 questions) may impose further restrictions on staff time and patients' willingness and ability to self-complete such a measure in the context of additional assessments and examinations.

A more recent study conducted by Hides et al. (2007) examined the performance of Kessler-10 (K-10) and Patient Health Questionnaire (PHQ) with a sample of drug users in Australia. These investigators recommended the use of both measures to enhance the detection of depression in injecting drug users based on an overall predictive accuracy of 76.7% for the K-10 and 78.6% for the PHQ (Hides et al., 2007). It is unclear, however, if the cross-sectional design allowed for an accurate detection of transient syndromes which may have inflated the predictive power of screening tests, in what has been described as 'spurious comorbidity bias' in cross-sectional association studies (Smoller et al., 2000). Franken and Hendriks (2001), for example, found that post-detoxification psychiatric diagnostic tests were more reliable than pre-detoxification tests, demonstrating that prospective cohort designs may be warranted to adequately assess the specificity of diagnostic tests with substance users.

In brief, despite the significant prevalence and impact of comorbidity, little evidence exists to support the use of brief depression screening questionnaires in mainstream substance misuse services in the UK. This study aimed to test the validity and reliability of the Patient Health Questionnaire (PHQ-9 and PHQ-2) in a sample of outpatients accessing treatment. It was conducted as part of the CCAS programme (*Case-finding and Comorbidity in Addiction Services*), a broader research project focusing on common mental disorders in community drug treatment.

2. Methods

2.1. Design

We sought to compare the accuracy of brief screening tools with respect to a criterion gold standard diagnostic assessment in a cross-sectional sample of outpatients. A prospective follow-up phase enabled us to additionally investigate test-retest reliability after 4–6 weeks, with reference to DSM-IV criteria for differential diagnosis (American Psychiatric Association, 2000) and the 'watchful wait' period recommended in the NICE guidelines for depression (NICE, 2010).

2.2. Context and participants

The setting was a mixed statutory and voluntary sector community drug treatment service (CDTS) in Leeds, UK. The City and South CDTS enables access to medical care, structured care co-ordination and psychosocial interventions following national treatment guidelines (Department of Health, 2007). The service engages approximately 640 patients per year, most of whom use heroin, alcohol, crack and other substances. Multiple social problems are pervasive in this treatment population, which require the team to work closely with social workers, criminal justice services, mental health teams, housing and employment support services.

A key aim of this study was to recruit a representative sample of patients accessing mainstream addiction treatment. To achieve this, we had wide inclusion criteria and recruited during a full calendar year, which meant that patients at various stages of treatment and with a range of needs had equal probability of participating. We excluded patients with psychotic disorders or bipolar disorder, consistent with the CCAS programme's focus on common mental disorders.

2.3. Measures

2.3.1. Patient Health Questionnaire (PHQ)

The PHQ has been extensively validated and is considered a reliable screening and outcome measure for depression (Gilbody et al., 2007a; Kroenke et al., 2001; Löwe et al., 2004). The 9 item version provides a total severity score ranging from 0 to 27, where scores of 5, 10, 15 and 20 represent mild, moderate, moderately severe and severe depression. A score above 10 has been proposed as providing the best trade-off between sensitivity (88%) and specificity (88%) for a diagnosis of major depression (Kroenke et al., 2001). The PHQ-2 is an abridged version and a score of 3 is recommended as the optimal cutpoint for screening purposes (Kroenke et al., 2003).

2.3.2. Revised Clinical Interview Schedule (CIS-R)

The CIS-R is a gold standard structured diagnostic interview that can be administered by suitably trained lay interviewers with the help of a computer interface (Lewis et al., 1992). This test elicits responses pertaining to 14 symptom areas matched to ICD-10 diagnostic criteria (World Health Organisation, 1992). It can be reliably used to assess 6 specific non-psychotic disorders: generalised anxiety disorder, mixed anxiety and depressive disorder, depressive episode, phobias, obsessive-compulsive disorder, and panic disorder. Up to two diagnoses (primary and secondary) are generated based on a symptom matching and scoring algorithm, where a score of 12 or more indicates significant severity of symptoms and a score above 18 warrants treatment. The CIS-R has been used as a diagnostic measure in the national Psychiatric Morbidity Surveys conducted in the UK (McManus et al., 2009; Meltzer et al., 1995), and also in addictions research (Gilchrist et al., 2005).

2.3.3. Secondary measures

Additional measures included the Treatment Outcome Profile (TOP; Marsden et al., 2007), the Severity of Dependence Scale (SDS; Gossop et al., 1995) and brief semi-structured questions about medication use.

2.4. Procedure

Following ethical approval from an independent research ethics committee, patients were recruited during routine contacts with the service using a standard study information leaflet. Consenting participants were invited to self-complete brief questionnaires in a confidential interview room, and staff support was provided for people who could not do so unassisted. Participants were then asked to partake in a diagnostic interview (CIS-R) conducted by trained clinical staff, followed by an opportunity to discuss the test results and any necessary assistance or treatment. Participants were also invited to participate in a retest appointment 4–6 weeks later. Supermarket vouchers valued at £10 were offered at both baseline and follow-up appointments to incentivise participation in the study.

2.5. Data analysis

We investigated the psychometric properties of the PHQ-9 and PHQ-2 and assessed the performance of these measures relative to the CIS-R. Receiver operating characteristic (ROC) curves were generated to assess the overall performance of tests with reference to the area under the curve (AUC) statistic. We calculated a minimum sample of 70 to reliably conduct ROC curve analyses, according to the sampling method proposed by Flahault et al. (2005) and in reference to test sensitivity/specificity values and confidence intervals reported in a UK primary care validation of the PHQ (Gilbody et al., 2007b). Sensitivity, specificity, predictive power and likelihood ratios were computed as indicators of diagnostic validity for the optimal cutpoints identified using the ROC method. Validity was further examined by correlating the measures against the gold standard CIS-R measure (convergent validity) and the SDS which theoretically measures a distinct construct (discriminant validity). The reliability of these measures was tested in two ways: Cronbach's alpha was used to test internal consistency and intra-class correlations were used to assess test-retest reliability. Finally, Youden's index was calculated to summarise the overall test accuracy using the formula: 1 − ((false positive rate) + (false negative rate)), where an upper index of 1 represents a perfect test, and a lower index of −1 represents a flawed test.

3. Results

We invited 162 patients to partake in the study. A total of 103 participated, 60 of whom also completed retests after 4 weeks. Only 3 patients expressly declined participation and a further 56 failed to attend their planned appointments. Table 1 describes demographic and clinical characteristics of the participating sample.

Most participants were unemployed (84%), males (77%) and of white British background (93%) with a mean age of 35. The most frequently used substances were alcohol, heroin, cannabis and crack, with 61% of respondents reporting poly-substance use and only 9% reporting abstinence in the last month. A total of 49% met diagnostic criteria for major depression, and 26% out of the total sample met criteria for mixed depressive and anxiety disorder according to CIS-R test results. Time in treatment ranged from new admissions up to 5 years, with 51% engaging under and 49% over a 12 month period. These demographic and treatment characteristics are comparable to national trends in community drug treatment (Gossop et al., 1997).

Table 1
Sample characteristics.

N = 103		
Characteristics	%	Mean (range)
Demographics		
Age		35 (23–54)
Male	77	
White British	93	
Unemployed	84	
In training or education	5	
Acute housing problem	11	
Substance use at any level (in the last month)		
Alcohol	57	
Heroin and other depressants[a]	68	
Crack and other stimulants[b]	33	
Poly-substance use	61	
Injecting	30	
Level of use		
Abstinent	9	
Using 1–2 times per week	37	
Using 3–4 times per week	15	
Using 5–7 times per week	39	
Treatment		
Substitute prescription	95	
Antidepressants	26	
Weeks in treatment		79 (0–278)
In treatment < 4 weeks	17	
In treatment < 12 weeks	27	
In treatment < 12 months	51	
In treatment > 12 months	49	

[a] Heroin, cannabis, diazepam, benzodiazepine, ketamine, and co-codamol.
[b] Crack, cocaine, amphetamine, and ecstasy.

ROC curves displayed in Fig. 1 represent the diagnostic accuracy of PHQ-9 and PHQ-2 across the full range of scores. PHQ-9 was the most accurate measure, with a significant AUC value of .86 (.79–.93) and the best trade-off between sensitivity (81%) and specificity (75%) at a cutpoint of 12. The performance of PHQ-2 was less impressive, with an AUC value of .75 (.65–.84) and more modest sensitivity (68%) and specificity (70%) values at a cutpoint of 3. According to the psychometric properties presented in Table 2, respondents classified by PHQ-9 as cases had an 84% probability of having a depressive disorder and those with scores below the cut-off had a 71% probability of not having a diagnosable depression. In contrast, the corresponding positive and negative predictive values for PHQ-2 hardly improve on a 50% probability of accurate classification. PHQ-9 had high internal consistency indicated by an alpha value above the conventional cutpoint of .70 (Nunnally, 1970) and its retest reliability was fairly robust (ICC = .78). In comparison, the shorter version had an alpha value of .64 and modest retest reliability (ICC = .66). Likelihood ratios and Youden's index are also presented in the table, corroborating the greater reliability of the 9 item measure in this particular sample. There was a significant positive correlation between PHQ-9 and CIS-R ($r = .76$, $p < .001$), indicating strong convergent validity. PHQ-9 was also significantly correlated to SDS ($r = .38$, $p < .001$), although the coefficient value suggests a weak association, indicative of good discriminant validity. The same pattern was observed for PHQ-2 when correlated to CIS-R ($r = .58$, $p < .001$) and SDS ($r = .25$, $p = .01$), but the associations were weaker.

4. Discussion

4.1. Limitations

We sought to investigate the validity and reliability of brief depression screening tools in a representative sample of drug and alcohol users in routine outpatient treatment to maximise clinical relevance and external validity. Taking a pragmatic approach, we used incentives and opportunistic recruitment which may have possibly excluded some patients who are more difficult to engage and who may have more complex or chaotic problems. Despite this potential source of recruitment bias, demographics, clinical factors and drug use patterns in this sample were broadly comparable to trends reported in national drug treatment outcomes research (Gossop et al., 1997; Jones et al., 2007).

Another important consideration worth noting is our choice of diagnostic interview (CIS-R) as the criterion standard against which to validate the use of brief questionnaires. As previously described, the CIS-R has been extensively validated and used in epidemiological surveys as a psychiatric diagnostic instrument. However, unlike some interview schedules that specifically address comorbid addictions such as PRISM (Hasin et al., 1998), AUDADIS-IV (Grant and Dawson, 2000) and SSAGA (Bucholz et al., 1994), CIS-R does not probe for the temporal sequencing of substance use and other axis I disorders, or the pervasiveness of psychological symptoms in periods of abstinence from alcohol or drugs. Such methods are often advocated to detect drug-induced mental disorders (Schuckit, 2006; Schuckit et al., 1997). Whilst acknowledging this limitation, we point to recent research based on sophisticated semi-structured interviewing conducted by psychologists and psychiatrists using the PRISM schedule, concluding that drug-induced anxiety and affective disorders are fairly uncommon compared to induced psychotic symptoms (Torrens et al., 2011). We therefore contend that the potential false positive rate that may be related to our choice of diagnostic interview is at worst modest, and at best compensated for by our efforts to evaluate retest reliability after a watchful wait period.

A further limitation concerns the relatively short follow-up period in this study, which we considered to be concordant with assessment guidelines (APA, 2000; NICE, 2010), but insufficient to describe a natural history of patterns of symptom stability and change over longer periods of routine addiction treatment.

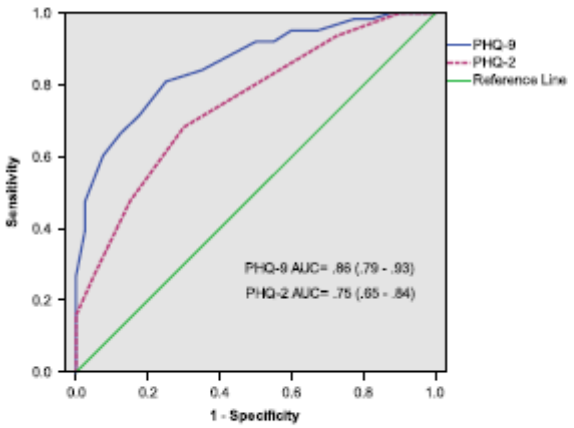

Fig. 1. ROC curves.

5. Conclusions

Mindful of some limitations described above, we take a cautiously optimistic view about the utility of brief case finding measures. Our results support the use of PHQ-9 as a measure with high internal consistency, acceptable retest reliability and good diagnostic accuracy only modestly lower to that reported by Gilbody et al. (2007b) in a UK primary care sample (sensitivity = 91.7%, specificity 78.3%). Our correlational analyses also indicate that the PHQ-9 has strong criterion validity and acceptable discriminant validity. Furthermore, the present results concur with those reported by Hides and collaborators who specifically tested PHQ-9 in a sample of injecting drug users, albeit in a different country and healthcare system (Hides et al., 2007). In contrast, our analyses of the ultra-brief version of this measure (PHQ-2) are less favourable and we cannot therefore confidently advocate using the abridged questionnaire.

5.1. Clinical and research implications

Brief depression screening tools including the PHQ-9 are commonly used in general practice settings and are advocated by the UK's general practice contract quality and outcomes framework (QOF) as a means of enhancing detection in high risk populations (British Medical Association, 2006). This

Table 2
Psychometric properties of depression screening tools in addiction treatment.

	Cronbach's α	ICC	Cutpoint	Sensitivity	Specificity	+PV	−PV	+LH	−LH	Youden's index
PHQ-9	0.84	0.78	12	0.81	0.75	0.84	0.71	3.24	0.25	0.56
PHQ-2	0.64	0.66	3	0.68	0.70	0.54	0.57	2.10	0.47	0.36

ICC = intra-class correlation; PV = predictive value; LH = likelihood ratio.

questionnaire is also widely used in routine psychological therapy services working under the national IAPT (*Improving Access to Psychological Therapies*) programme as a routine outcome measure (Clark et al., 2009). The present study provides empirical support for the use of such questionnaires in the addictions field.

There are, however, important barriers and problems that must be considered before depression screening can be fully embedded in routine drug treatment services. Common criticisms and objections to questionnaire-driven screening in primary care are as follows: an overestimation of the prevalence of depression when using PHQ-9 (Kendrick et al., 2009), limited evidence of improved outcomes or treatment take-up following screening (Gilbody et al., 2001, 2005; Gilchrist and Gunn, 2007), and suggestions by clinicians that relying on questionnaires undermines clinical judgement (Dowrick et al., 2009) and possibly interferes with the therapeutic relationship (Leydon et al., 2011). We therefore advocate a considered and strategic introduction and evaluation of screening supported by training of non-specialist staff in basic differential diagnosis strategies, development of treatment pathways into psychiatric and psychological services with clear criteria for collaborative care, and also informed by qualitative data and consultation with service users to ensure that screening is delivered in a manner acceptable to this patient population.

Further validation studies using interviews such as PRISM would strengthen the evidence base for the reliability and utility of case finding tools, particularly with more hard-to-engage groups such as those affected by homelessness, those in criminal justice services and harm reduction services. Future observational studies with repeated testing over longer periods would help to increase our understanding of the natural history of depression and its complex interactions with substance use patterns, as well as the utility and limitations of PHQ-9 as an outcome measure in drug-using populations.

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Conflict of interest

All authors declare that they have no conflicts of interest in the conduct of this research.

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Appendix K – Patient stakeholder reference group minutes

Recovery Research Team meeting – Friday 17th May 2013

Present: [redacted], [redacted] [redacted], [redacted], [redacted], [redacted]

Agenda:

- Introductions
- Update on recovery fund application
- New additions to research team
- Presentation on the design process
- Organisation of content
- Plans for next meeting

Introductions

[redacted] – Service User Representative / volunteer for Leeds Community Drug Partnership

[redacted] – Peer Mentor for Leeds Community Drug Partnership

[redacted] - Peer Mentor for Leeds Community Drug Partnership

[redacted] – Dual Diagnosis Expert Reference Group Representative

Update on recovery fund application

SG advised team he had started completing an application for the Recovery Fund in an attempt to secure funding to finance the design and evaluation of the Head Injury applet. Deadline for funding application date 24th May.

New additions to research team

SG notified the team that he would be seeking further guidance from Dr Rebecca Randall at The University of Leeds over usability evaluation method design for the study. SG will be meeting with Dr [redacted] on 30th May. It has been agreed SG will feedback outcome of meeting at next planned recovery research team meeting. Team members have been notified Dr [redacted] is still attempting to identify a potential post graduate student within The University of Leeds who has the necessary technical skills to support the project.

Presentation on the design process

Please see attachments for PowerPoint slides and accompanying script. Presentation was delivered by LF.

Organisation of content

It has been agreed a parallel design method will be applied to initial applet development. This involves team members bringing together their thoughts on the content of the applet and how this information will be organised. The OSU TBI ID semi-structured interview has been provided and will be used as the template for applet design. To make the process more manageable it is has been agreed we will focus initially on the first section of the interview page one. Team members are encouraged to be as creative as possible and have the opportunity to discuss their ideas with SG prior to our next meeting. When the team comes together we will share our ideas and choose the design which best suit service user needs, which team members will present.

Plans for next meeting

The next meeting has been planned for 14th June at 2pm at St Anne's Resource Centre. The organisation of content for section one will be finalised and preliminary discussions for section two will commence and the exercise on parallel design will be continued.

Recovery Research Team meeting – Friday 14th June 2013

Present: [redacted], [redacted], [redacted], [redacted], [redacted], [redacted]

Agenda:

- Update on recovery fund application
- Service user newsletter
- Presentation on page layout guidelines
- Reviewed initial paper based prototype of head injury app
- Plans for next meeting

Update on recovery fund application

Feedback from Recovery Fund application on Wednesday 5th June. Please find attached letter on decision of application. Unfortunately we were not successful this time in securing funding. However there will be a second opportunity to apply this year.

Service user newsletter

SG wrote a brief article outlining the head injury app project with the intention of raising awareness of traumatic brain injury through the service user newsletter. A brief summary describing some of the findings from the smart phone survey were included.

Presentation on page layout guidelines

SG delivered brief presentation of page layout following usability.gov guidelines. Please see attachments for PowerPoint slides and accompanying script.

Reviewed initial paper based prototype of head injury app

The following feedback from ERG was received. Key points included:

- YES and NO buttons should have different colours (suggestions: green = YES, red = NO)
- screen layout should be black writing on white background
- avoid bright colours
- large font best
- all the screen features need to be customisable

Recommendations for specific slide changes can be found below:

- All slides with an 'A' designation require a change in language in order to make the question more descriptive, e.g. 'Have you had any physical injuries in the past (time period)?'
- All slides with a 'B' designation require a change in language, e.g. 'How many physical injuries?'
- All slides with a 'J' designation also require a change in language, e.g. 'Did you seek medical help? Or did another person seek medical help on your behalf?'
- Include a "Don't know" option for slides E, F, H, I, J & L
- For slide P, tick boxes should be removed and replaced with YES/NO options
- Slide I requires a change in language, e.g. 'At the time of the injury were you drinking more heavily than normal and do you think this could be why you cannot remember?'

A concern was expressed over the length of time it would take to complete the app and the following suggestions were made:

- The inclusion of a progress status bar at the top of the screen. The bar would have 5 marker points which would correspond to the 5 levels of memory recall the respondent would progress through, e.g. Have you had any physical injuries in the past 3 months/12 months/5 years/any other injuries/whilst serving in the armed forces? Although this may need to be reviewed as it was suggested the progress status bar could be a potential demotivator if it is not progressing quickly.
- A change to the algorithm to speed up the progress so if respondents select 'NO' for slides E & H, the respondent will either go to slide A or slide C
- To help the respondent keep track of the number of relevant injuries they have disclosed, there will be a screen which visually displays in a graphical format all injuries described at that point in the app. The summary screen could appear after slides P and/or a button on the screen could be selected and accessed at any stage in the app to help the respondent monitor their progress.
- To reduce the number of selects the respondent has to make on each screen, once they have selected the necessary option the app will advance to the next screen automatically without having to select the continue button. The back button option will still be available for each screen.

Plans for next meeting

The next meeting has been planned for 12th July at 2pm at St Anne's Resource Centre.

The following agenda has been suggested:

- update on recruitment for clinical expert reference group
- appraise revisions to paper based prototype
- Steve Ellis to provide artist mock-ups of screen graphical design
- appraise content, layout and format of home screen
- feedback following consultation with Nick Crohn (expert in cybercrime and medical app development)
- discuss potential inclusion for content of "about head injury" e-book

Recovery Research Team meeting – Friday 12th July 2013

Present:

[redacted] and [redacted]

Apologies:

[redacted], [redacted] and [redacted]

Agenda:

- update on recruitment for clinical expert reference group
- appraise revisions to paper based prototype
- [redacted] to provide artist mock-ups of screen graphical design
- appraise content, layout and format of home screen
- feedback following consultation with [redacted] (expert in cybercrime and medical app development)
- discuss potential inclusion for content of "about head injury" e-leaflet

Update on recruitment for clinical expert reference group

SG was able to confirm 3 members of staff within City & South CDTS have agreed to contribute to the clinical ERG. They are [redacted] (recovery coordinator), [redacted] (recovery coordinator) and [redacted] (general practitioner). The first clinical ERG meeting has been scheduled for 29th July.

Appraise revisions to paper based prototype

GS found the amended HIT app version 1.2 acceptable with no major design amendments. A potential problem with the data collection method has been identified by SG, e.g. it is not clear to the respondent completing the app if they specify more than one injury on screen B which injury they are referring to when completing screen C ('Select type of injury'). This led to HIT app version 1.3 where the respondent is now instructed on screen C: 'First injury – select what happened', 'Second injury – select what happened', etc.

A colleague who has an interest in art and design, [redacted], agreed to appraise the app and made the following recommendations (please see email dated 17th July). I would be grateful if you have the opportunity to take a look at the current HIT app version 1.4 so we can discuss at next planned meeting.

[redacted] to provide artist mock-ups of screen graphical design

Pending

Appraise content, layout and format of home screen

GS found the format and layout of the home screen acceptable, reiterating the importance of ensuring the design is kept simple and straightforward.

Feedback following consultation with Nick Crohn

Nick has agreed to serve as a consultant as the project progresses. He has a background in criminology and specialises in cyber security. From what I have described to him he believes an app is the correct format for the project brief.

As the app will be collecting data and making a clinical decision, consider the data processing method, e.g. the way in which the app will be making clinical decisions.

We need to pay attention to cyber security as this will influence whether we opt for IOS (Apple) or android operating systems (what phones the app will work on). IOS will validate your security and offer you greater protection to cyber-attack. Android as it is open source is more vulnerable to cyber-attack so considerable attention needs to be given to data security especially if you are storing data on a server. He believes the risk can be mitigated if the app is just sending packets of data and a hardware firewall is used. Hosting the app on the university website will offer increased protection against potential attacks.

Discuss potential inclusion for content of "about head injury" e-leaflet

GS was provided with an example paper based leaflet published by the Disabilities Trust on brain injury amongst people who are homeless. GS really liked the way in which the health literature delivered the information through getting the reader to think about a series of easy to read quick questions. He found the colours used pleasing and engaging, stating we should consider adopting a similar approach to the "about head injury" e-leaflet

Plans for next meeting

The next meeting has been scheduled for 9th August at 2pm at St Anne's Resource Centre. The following agenda has been suggested:

- to review proposed data processing method
- update on recruitment for clinical expert reference group
- appraise revisions to paper based prototype
- discuss potential inclusion for content of "about head injury" e-leaflet

- appraise sound effects for HIT app

Recovery Research Team meeting – Friday 9th August 2013

Present: [redacted], [redacted], [redacted] and [redacted]

Apologies: [redacted]

Agenda:

- to review proposed data processing method
- update on recruitment for clinical expert reference group
- appraise revisions to paper based prototype
- discuss potential inclusion for content of "about head injury" e-leaflet
- appraise sound effects for HIT app
- recovery fund appeal

To review proposed data processing method

SG provided a brief overview of the HIT app's data processing method. Please see attached document for detailed overview for data processing. SG was able to confirm there may be a web version of the prototype HIT app available for next meeting.

Update on recruitment for clinical expert reference group

SG advised team the clinical ERG met on the 29th July and they have begun the parallel design process. The clinical ERG will next be meeting on 16th August with their initial design ideas.

Appraise revisions to paper based prototype

GS, MP and SB found the latest HIT app version 1.4 acceptable with one minor amendment. On screens J and L the colloquialism "blues" was used and general consensus was that "benzos" would be more appropriate to cover a wider range of narcotics. For screens I, J, K and L it needs to be made obvious to the respondent completing the HIT app that the screens have changed as they are very familiar in wording and layout.

Discuss potential inclusion for content of "about head injury" e-leaflet

MP and SB agreed with GS's comments from last meeting (see minutes 12th July). SG suggested the "about head injury" e-leaflet should offer increasing levels of detail, e.g. basic and learn more options. A working example of an e-leaflet will be provided by SG prior to next meeting. The team found this to be acceptable.

Appraise sound effects for HIT app

Pending

Recovery Fund appeal

It has been agreed an appeal will be made to the Recovery Fund alongside an application to the Yorkshire Venture Philanthropy Fund where grants up to £5000 are available to social enterprise projects. SG to complete applications prior to next meeting.

Any other business

The team are keen for the prototype HIT app to undergo usability testing. SG agreed he would provide more detail about the evaluation method (cognitive walkthrough technique) at next session. Furthermore the team have agreed to support SG in the completion of the University of Leeds ethical approval for the School of Healthcare Research Ethics Committee (SHREC) which needs to be actioned prior to usability testing.

Plans for next meeting

The next meeting has been scheduled for 6th September at 2.30pm at St Anne's Resource Centre. The following agenda has been suggested:

- appraisal of prototype HIT app (web version)
- update on clinical expert reference group
- appraisal of "about head injury" e-leaflet working model
- review funding applications
- introduce usability evaluation methods
- review SHREC application

Recovery Research Team meeting – Friday 6th September 2013

Present: [redacted], [redacted], [redacted] and [redacted]

Apologies: [redacted]

Agenda:

- appraisal of prototype HIT app (web version)
- update on clinical expert reference group
- appraisal of "about head injury" e-leaflet working model
- review funding applications
- introduce usability evaluation methods
- review SHREC application

Appraisal of prototype HIT app (web version)

Unfortunately the software application was not ready for appraisal today. The software developer experienced some complications with respect to formatting. The version he had developed runs on a more up to date version of Windows. This meant it was not feasible to appraise the app as the CDTS operating system is currently still Windows XP (old version of Windows). It has been agreed the software developer will provide an XP version of the HIT app for next ERG meeting.

Update on clinical expert reference group

The clinical ERG has recruited a further 2 members. Patricia Fas (service manager) and Leon Walters both from the Big Issue. LW has kindly agreed to generate a soundscape for the app for when respondents select various functions.

SG advised the clinician version of the HIT app will be approved by the 7th October ready for coding.

Appraisal of "about head injury" e-leaflet working model

MP, SB and GS felt the more detailed version of the e-leaflet was too technical and the language needed amending. MP believed clinical language should remain but a clear explanation of the terminology should be provided, e.g. 'tangential thinking' and 'initiation problems'. SB stated how each screen should have the brief definition of TBI, e.g. "Traumatic Brain Injuries or TBI are injuries caused by a blow to or violent movement of the head or neck", just in case a respondent only chooses to select 'Learn More' further into the basic version of the e-leaflet which would mean they

would miss the initial introductions to head injury. SB, MP and GS believed the order in which the screens connect should be rearranged, e.g. swap detailed versions of pages 2 and 3 to better coincide with content in basic version.

Review funding applications

SG apologised that due to work commitments he was unable to resubmit an appeal to the Recovery Fund application. However SB kindly agreed to complete the Yorkshire Venture Philanthropy Fund small grants application form. SG to forward SB electronic application via email and to provide supplementary information.

Introduce usability evaluation methods

SG provided ERG with recruitment procedure flow diagram for service user participants. The ERG considered the recruitment process to be acceptable.

SG provided ERG with details describing the cognitive walkthrough method. The ERG considered the method of usability assessment to be acceptable however there was some uncertainty as to whether some potential participants might find the think aloud technique too cognitively demanding.

Please find attached hand-outs provided at meeting.

Review SHREC application

Pending

Any other business

Photograph taken of ERG for future research promotion.

Plans for next meeting

The next meeting has been scheduled for 11th October at 2.30pm at St Anne's Resource Centre. The following agenda has been suggested:

- appraisal of prototype HIT app (web version)
- appraise sound effects for HIT app
- appraisal of "about head injury" e-leaflet version 1.1
- review funding applications
- review SHREC application

Appendix L – Staff stakeholder reference group minutes

Recovery Research Team meeting – Friday 16th August 2013

Present:

[redacted], [redacted] and [redacted]

Apologies:

[redacted]

Agenda:

- Reviewed initial paper based prototype of head injury app
- Presentation on page layout guidelines
- Plans for next meeting

Reviewed initial paper based prototype of head injury app

EF and SG brought initial design concepts (please find attached). Some of the concept designs were merged and a third design was developed, inspired by the NHS symptom checker. Primary focus was on layout. It was thought having the guidance section equal to the interview questions created confusion over which parts of the screen were active. Potential solutions:

- Instructions in how to guide the interviewer could appear at the bottom of the screen perhaps in a speech bubble coming from an icon, either a doctor (white lab coat, stethoscope and clipboard) or brain with question mark superimposed over the top (see example below).
- In the first open field box in a faint box there could be an example (e.g. car crash)

SH felt the team started to amend some of the content in the respective designs. SH felt 'Ask the patient' should be removed as she did not like the instruction. Both EF and SH wanted there to be someway of numerating the screens so they could have some way of measuring how far they had progressed through the interview and some mechanism of being able to return back to different stages in the interview. One potential solution could be an 'app map' which could be what you find similar to websites.

Suggested changes for initial screen to guidance notes include:

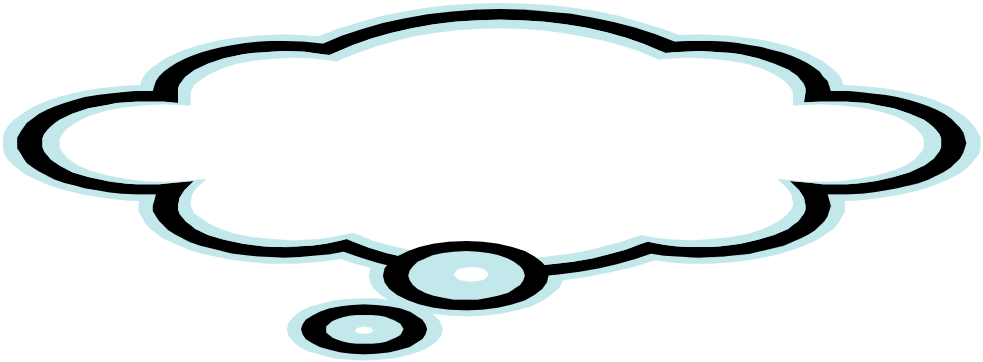
‘Types of injuries you may include are:

- those sustained in a car accident
- falls
- blasts
- those sustained playing sports’

It has been agreed the team will exchange emails on suggested amendments to content as this process is time consuming.

In the past 3 months have you had any physical injuries?

List the injuries	Age
1. _____	
2.	
3.	
4.	



<u>Presentation on page layout guidelines</u>

EF and SH reviewed PowerPoint slides prior to meeting and applied learnings from this. EF felt it was important to have navigation points ‘back’ and ‘continue’ at the top of the screen as she felt this was important layout information. Further points over layout and content will be discussed via email exchange prior to next meeting.

KC made contact via email and in summary provided some of the following comments. KC thought there should be a feedback system integrated within the app enabling service users and clinicians to make comments on their experience of the app. KC believes some consideration should be given to how the app will be disseminated, e.g. nationwide or local, stating benefits and limitations of each:

- nationwide advantages are that it may have a wider audience however this may mean that without good national advertising it may not be used as nobody knows about it.
- local usage means advertising the app to the right audience is possible. It is easier to pilot. It can include relevant information and web links to local referral pathways.

KC believes it would be useful for clinicians to be able to print out test results with details and advice on what further steps should be taken. The final comments from KC perhaps relate more closely to the 'about head injury' e-leaflet which will be embedded within the app:

- brief introduction as to how head injuries occur
- web links for support groups, charities and further educational information

<u>Plans for next meeting</u>

- Confirm final paper-based prototype design prior to coding and usability testing
- Development team will discuss potential inclusion of content to head injury e-leaflet from clinical perspective

Next meeting has been scheduled for 9th September at 3pm at St Anne's.

Recovery Research Team meeting – Monday 9th September 2013

Present:

[redacted], [redacted] and [redacted]

Apologies:

[redacted] and [redacted]

Agenda:

- Confirm final paper-based prototype design prior to coding and usability testing
- Development team to discuss head injury e-leaflet content from clinical perspective
- Biomarker as method for detecting TBI
- Plans for next meeting

Confirm final paper-based prototype design prior to coding and usability testing

Primary focus of meeting was to review content of clinical version HIT app (please find attached version 1.1). Reviewed aim of research, e.g. to design and evaluate a web-based application for detecting self or proxy reports of TBI exposure over a lifetime.

The TBI case finder will be:

- brief
- non-invasive
- self-completing and mitigate the need for a trained professional
- accessible to a range of different service providers
- portable and can be used in the community
- not dependent on reading ability

TF and KC reflected on the importance of avoiding technical terminology as the potential end users will come from a range of health and social care backgrounds with varying degrees of knowledge of TBI. KC kindly agreed to lend some clinical expertise in how the HIT app could process clinical data.

SG explained how the HIT app will be asynchronous, which means national data about referral pathways to memory services can be stored by a remote server and accessible according to respondent post code providing locally relevant information accounting for regional differences. This feature is available with the NHS Symptom Checker.

SG agreed to circulate current clinical version of the HIT app to ERG members who couldn't attend for final comments.

Development team to discuss head injury e-leaflet content from clinical perspective

SG emailed clinical ERG e-leaflet on the 12th September and is currently awaiting feedback.

Biomarker as method for detecting TBI

SG advised clinical ERG that he would be meeting with Helen McDonald specialist speech and language therapist based at Chapel Allerton hospital neuro rehabilitation on 3rd October.

It is the development team's ambition to integrate a biomarker (speech analysis) alongside a gold standard retrospective self-report measure for TBI detection. How SG envisages HM will be able to support this work is through her highly specialist knowledge relating to brain trauma rehabilitation and the consequences this can have on speech and language.

Firstly, it would be useful to know what are the potential confounders, e.g. other forms of acquired brain injury or neurological health conditions, which could have a similar clinical presentation to TBI. Secondly, what are the clinical markers you would be initially attempting to identify following a TBI event. Through digital recording and speech recognition software it is hoped learning algorithms will be able to replicate this initial speech and language screening process making early detection of mild-moderate TBI more feasible triangulated with lifetime exposure to head injury.

SG agreed to forward KC links to Max Little and his research team who are using speech analysis for early detection of Parkinson's.

Plans for next meeting

- Confirm final paper-based prototype design prior to coding and usability testing
- Development team to discuss head injury e-leaflet content from clinical perspective
- Update on biomarker as method for detecting TBI

Next meeting has been scheduled for 7th October at 3pm at St Anne's.

Appendix M - Stakeholder presentation script

Slide 1:

Have several team members independently propose designs and use the best elements from each design.

Do not have individuals make design decisions by themselves or rely on the ideas of a single team member. Most designers tend to adopt a strategy that focuses on initial, satisfactory, but less than optimal, solutions. Group discussions of design issues (brainstorming) do not lead to the best solutions.

The best approach is parallel design, where team members independently evaluate the design issues and propose solutions. Attempt to 'saturate the design space' before selecting the ideal solution. The more varied and independent the ideas that are considered, the better the final product will be.

Slide 2:

Involve service users to improve the completeness and accuracy of service user requirements.

One of the basic principles of user-centred design is the early and continual focus on service users. For this reason, service user involvement has become a widely accepted principle in the development of usable systems. Involving service users has the most value when trying to improve the completeness and accuracy of user requirements. It is also useful in helping to avoid unused or little-used system features. User involvement may improve the level of user acceptance, although the research is not yet clear that it does in all cases. There is little or no research suggesting that user involvement leads to more effective and efficient use of the system. To summarize, service users are most valuable in helping designers know what a system should do, but not in helping designers determine how best to have the system do it.

Slide 3:

If user performance is important, make decisions about content, format, interaction, and navigation before deciding on colours and decorative graphics.

Focus on achieving a high rate of user performance before dealing with aesthetics. Graphics issues tend to have little impact, if any, on service users' success rates or speed of performance.

Slide 4:

Identify and clearly articulate the primary goals of the applet before beginning the design process.

Before starting design work, identify the primary goals of the applet (educate, inform, entertain, sell, etc.). Goals determine the audience, content, function, and the applet's unique look and feel. It is also a good idea to communicate the goals to, and develop consensus for the applet goals from, management and those working on the applet.

Slide 5:

Provide content that is engaging, relevant, and appropriate to the audience.

Content is the information provided on an applet. Do not waste resources providing easy access and good usability to the wrong content. One study found that content is the most critical element of an applet. Other studies have reported that content is more important than navigation, visual design, functionality, and interactivity.

Slide 6:

After ensuring that content is useful, well-written, and in a format that is suitable for the applet, it is important to ensure that the information is clearly organized. In some cases, the content on an applet can be organized in multiple ways to accommodate multiple audiences.

Slide 7 & 8:

Organizing content includes putting critical information near the top of the applet, grouping related elements, and ensuring that all necessary information is available without slowing the user with unneeded information. Content should be formatted to facilitate scanning, and to enable quick understanding.

Organize information at each level of the applet so that it shows a clear and logical structure to typical service users.

Designers should present information in a structure that reflects user needs and the applet's goals. Information should be well-organized at the applet level, page level, and paragraph or list level.

Good applet and page design enables service users to understand the nature of the applet's organizational relationships and will support service users in locating information efficiently. A clear, logical structure will reduce the chances of service users becoming bored, disinterested, or frustrated.

Slide 9:

Structure each content page to facilitate scanning: use clear, well-located headings; short phrases and sentences; and small readable paragraphs.

Applets that are optimized for scanning can help service users find desired information. Service users that scan generally read headings, but do not read full text prose–this results in service users missing information when a page contains dense text.

Studies report that about eighty percent of service users scan any new page. Only sixteen percent read each word. Service users spend about twelve percent of their time trying to locate desired information on a page.

To facilitate the finding of information, place important headings high in the centre section of a page. Service users tend to scan until they find something interesting and then they read. Designers should help service users ignore large chunks of the page in a single glance. Keep in mind that older service users (70 and over) will tend to scan much more slowly through an applet page than will younger service users (ages 39 and younger).

Slide 10:

Group all related information and functions in order to decrease time spent searching or scanning.

All information related to one topic should be grouped together. This minimizes the need for service users to search or scan the applet for related information. Service users will consider items that are placed in close spatial proximity to belong together conceptually. Text items that share the same background colour typically will be seen as being related to each other.

Use colour to help service users understand what does and does not go together. Colour coding permits service users to rapidly scan and quickly perceive patterns and relationships among items. Items that share the same colour will be considered as being related to each other, while items with prominent colour differences will seem to be different.

People can distinguish up to ten different colours that are assigned to different categories, but it may be safer to use no more than five different colours for category

coding. If more than ten different colours are used, the effects of any particular relationship will be lost.

Do not use colour alone to convey information.

Appendix N – Stakeholder presentation slides

Expert Reference Group

Parallel Design:

- many different people propose design solutions.
- Have several team members independently propose designs and use the best elements from each design.

How can I get involved?

- Service user led expert reference groups are most valuable in helping designers know what a system should do.

Design Priorities

If service user performance is main priority:

- Content
- Format
- Interaction
- Navigation

Primary goal of Head Injury applet

- To be able to screen patients in community drug treatment for traumatic brain injury.

Secondary Goal:

- To record a service user's lifetime exposure to injury which might include traumatic brain injury.
- To record more specific details about each injury e.g. type of accident, did it involve high velocity forces, and was there altered consciousness e.g. unconsciousness, dazed, confused, memory lapses.

Where to Start

Content is more important than:

- Navigation
- Visual Design
- Functionality
- Interactivity

Content

Content needs to be:

- Useful
- Well written
- Suitable

Organising Content

- Critical information near the top of the screen
- Group related elements
- Only provide necessary info
- Have a clear and logical structure

Objectives

Objectives should reflect:

- Service user need
- Applet goals

Quick Glance

Screen layout:

- Headings should be clear and well located
- Use short phrases and sentences
- Small readable paragraphs

Grouping Related Info and Functions

- Group by topic
- Info which is close together or has the same background colour are considered to be connected
- Use no more than 5 different colours for grouping related items

Appendix O – Patient information leaflet

RESEARCH PROJECT:

Head Injury Test app

Patient Information Leaflet

What is the research about?

We are designing and evaluating a mobile phone app which can be used to detect what injuries a person has experienced to their head or neck throughout their lifetime – the Head Injury Test app (HIT). This is important as head injuries could result in problems with:

- memory
- concentration
- managing feelings
- controlling impulses
- keeping a job
- fall out with family or those close to you

A mobile phone app is a computer program which can be used on certain types of mobile phone.

How can I help?

We need your help to ensure the HIT app is easy to use. We will video record your comments as you complete the HIT app. With your consent we might want to quote some of your comments as to what you thought about the HIT app when we publish the study's findings. Any comments you provide will remain completely anonymous and nobody will be able to tell you took part in the research. Other things we would like to know include:

- Were you able to complete all of the HIT app?
- How long did it take you?
- Did you need help?
- What did you like and dislike about the HIT app?

Why have you asked me and do I have to do it?

Anyone who is in your drug service who feels anxious and depressed is asked if they would like to take part as mental health problems can occur after a head injury. It is up to you if you want to do it or not. It doesn't affect your prescription and help with your drug or alcohol problem will stay the same.

What will happen if I take part?

You will be asked to complete the HIT app at your drug treatment service, and this should take about 30 minutes of your time. A member of the research team will give you lots of information about what is expected from you before you start.

If you are worried about a head injury you would still speak to your recovery coordinator or doctor. The HIT app has not yet been scientifically tested and we cannot be certain any results it provides are reliable. If we think things are getting worse for you like your health then we will give you helpful information and tell you how you can find more support. If we think you are at serious risk of hurting yourself we would speak to your doctor. We always try to speak with you first to get your permission.

What do I have to do if I want to take part?

With your permission your recovery coordinator will give us your contact details and we will call you on your phone to see if you have any more questions. If you would like to take part we will ask you a few questions about head injury and if you have experienced a head injury at some point in your life. We will ask your permission to post out a consent form to your home address. Please sign and post the participant consent form using the freepost envelope provided. Alternatively we could meet when you next attend your drug treatment service.

If you decide you don't want to do it and you have changed your mind you can call any one of us in the research team and let us know. If you don't want to do it you don't have to give us a reason why.

What could be bad for me if I take part?

The HIT app will ask you about injuries you might have suffered to your head or neck throughout your lifetime. This could be uncomfortable for you as it could make you think about difficult or unpleasant feelings or times in your life.

What could be good for me if I take part?

Your comments about the HIT app will help us improve the design, making the final version easier to use for people receiving drug treatment. What we learn from the research could help make the type of tools we use in the future better for people who have a head injury and drug or alcohol problems.

If I take part will it be confidential?

Yes, any information about you will be kept strictly confidential. Your test results will be kept on a secure computer database. Only the research team will be able to use the computer. We will need to keep a copy of your contact details so we can speak with you as you are taking part in the research. We will get some basic information about your drug treatment from your assessment records at the drug treatment service. Only the research team will be able to see this information about you (name, telephone number and address) until the end of the research in July 2015.

When the research ends, your personal information will be taken off the computer database and nobody will be able to tell you took part in the research when we write about what we found out.

If you would like to know more about the type of information we need for the research, anyone in the research team will be able to answer any questions you have.

Your doctor (GP) will not be notified if you decide to take part.

What happens at the end of the research?

At the end of the research we will know:

- how many people took part in the research
- what they thought about the HIT app
- how easy it was to use
- how we can improve the design of the HIT app

With your consent we may want to directly quote what you had to say about the HIT app, however your identity will remain anonymous. We would like to share what we have learned with lots of other people so the research will be published in scientific journals. We can give you a quick report of what we have learnt from this research.

What if there is a problem?

You can leave the research at any time. All you have to do is speak with a member of the research team and we will not ask you to participate in any further meetings or contact you for information. If you have any worries or you would like to know more please speak with a member of the research team. If you do not feel the information you are given was helpful or there is a problem or you would like to make a complaint please speak with the Principal Investigator.

Who has reviewed this study?

This study has been ethically reviewed by NRES Committee York and Humber – Leeds West.

Contact details

For further information in relation to the study please contact a member of the research team on:

Principal Investigator: Stuart Gore

Telephone: 0113 236 6610

Postal address: City & South CDTS, Top Floor, St Anne's Resource Centre, 66 York Street, Leeds, LS9 8AA

Research Supervisor: Dr. Bonnie Meekums

Telephone: 0113 343 9414

Postal address: Room 3.09, Baines Wing, School of Healthcare, University of Leeds, Woodhouse Lane, Leeds LS2 9JT

Research Supervisor: Dr. Greg Nolan

Telephone: 0113 343 9431

Postal address: Room 3.12, Baines Wing, School of Healthcare, University of Leeds, Woodhouse Lane, Leeds LS2 9JT

Research Supervisor: Professor Bill Montelpare

Email: wmontelpare@upei.ca

Appendix P – Clinician information leaflet

RESEARCH PROJECT:

Head Injury Test app

Clinician Information Leaflet

The purpose of the study

Trauma to the head or neck can cause Traumatic Brain Injury (TBI). It is common in people who are being treated for substance use problems. This group often go unrecognised as routine screening typically does not occur in CDT.

Neurological impairments associated with TBI include problems with concentrating, memory, social judgements and depression. Those who have combined TBI and substance use problems can benefit from getting access to specialist brain injuries rehabilitation treatment.

The aim of this study is to design and evaluate a mobile phone app for detecting TBI over a lifetime which is:

- brief
- non-invasive
- self-completing and mitigate the need for a trained professional
- accessible to a range of different service providers
- portable and can be used in the community
- not dependent on reading ability

How can I help?

Two groups of participants will be systematically recruited to evaluate the usability of the prototype Head Injury Test app (HIT). Patients in CDT who have been identified as having depressive symptoms and exposure to TBI and clinical members of staff who will have contact with patients who have been exposed to TBI. Both groups will test the HIT app in a controlled test facility located within a CDT setting. The HIT app will be based on principles of human centred design and evaluation to enhance adoption of the technology by service user groups and health practitioners. The study will run for 12 months.

We need your help to ensure the HIT app is easy to use. We will video record your comments as you complete the HIT app. Other things we would like to know include:

- Were you able to complete all of the HIT app?
- How long did it take you?
- Did you need help?
- What did you like and dislike about the HIT app?

Why have you asked me and do I have to do it?

Your participation is entirely voluntary and time will be made available for you to take part in the study.

What will happen if I take part?

You will be asked to complete the HIT app at your drug treatment service. An actor following a set script will adopt the role of a patient with a suspected history of head injury. You will be encouraged to think aloud when evaluating the prototype to identify problems, leading to new ideas for redesign. A member of the research team will give you lots of information about what is expected from you before you start.

What do I have to do if I want to take part?

An email will be sent to all clinical members of staff who conduct screening for TBI inviting them to consider taking part in the study. A clinician information sheet will be sent as an attachment with the email. Members of staff who express an interest will be

contacted within 1 week by the Principal Investigator to discuss the study. It is important that clinicians have an opportunity to discuss and clarify any questions thoroughly before considering whether or not they wish to participate and doing so with a person who is not directly responsible for their line management eases any undue pressure to participate. If the clinician agrees to take part in the study they will be provided with a consent form to complete and return to the PI.
If you decide you don't want to do it and you have changed your mind you can call any one of us in the research team and let us know. If you don't want to do it you don't have to give us a reason why.

What could be bad for me if I take part?

You will have to ask questions of a sensitive nature, e.g. injuries a service user might have suffered throughout their lifetime, and this could make you uncomfortable. However to minimise this experience you will be using the app with an actor who is following a set script.

What could be good for me if I take part?

Your comments about the HIT app will help us improve the design, making the final version easier to use for people receiving drug treatment. What we learn from the research could help make the type of tools we use in the future better for people who have a head injury and drug or alcohol problems.

If I take part will it be confidential?

Yes, any information about you will be kept strictly confidential. Your test results will be kept on a secure computer database. Only the research team will be able to use the computer. We will need to keep a copy of your contact details so we can speak with you as you are taking part in the research. We will get some basic information about you and only the research team will be able to see this information (name and work telephone number) until the end of the research in January 2015.

When the research ends, your personal information will be taken off the computer database and nobody will be able to tell you took part in the research when we write about what we found out.

If you would like to know more about the type of information we need for the research, anyone in the research team will be able to answer any questions you have. If you decide you would like to take part we will notify your line manager.

What happens at the end of the research?

At the end of the research we will know:

- how many people took part in the research
- what they thought about the HIT app
- how easy it was to use
- how we can improve the design of the HIT app

We may want to directly quote what you had to say about the HIT app, however your identity will remain anonymous. We would like to share what we have learned with lots of other people so the research will be published in scientific journals. We can give you a quick report of what we have learnt from this research.

What if there is a problem?

You can leave the research at any time. All you have to do is speak with a member of the research team and all your personal information will be removed from the database. If you have any worries or you would like to know more please speak with a member of the research team. If you do not feel the information you are given was helpful or there is a problem or you would like to make a complaint please speak with the Principal Investigator.

Contact details

For further information in relation to the study please contact a member of the research team on:

Principal Investigator: Stuart Gore

Telephone: 0113 236 6610

Postal address: City & South CDTS, Top Floor, St Anne's Resource Centre, 66 York Street, Leeds, LS9 8AA

Research Supervisor: Dr. Bonnie Meekums

Telephone: 0113 343 9414

Postal address: Room 3.09, Baines Wing, School of Healthcare, University of Leeds, Woodhouse Lane, Leeds LS2 9JT

Research Supervisor: Dr. Greg Nolan

Telephone: 0113 343 9431

Postal address: Room 3.12, Baines Wing, School of Healthcare, University of Leeds, Woodhouse Lane, Leeds LS2 9JT

Research Supervisor: Professor Bill Montelpare

Email: wmontelpare@upei.ca

Appendix Q - Cognitive walkthrough test administrator script

Instructions:

In a few moments I am going to ask you to fill in this survey using this [tablet/PC].

When you fill in the survey I need you to tell me about:

- things you are reading on the screen
- what it is you are thinking
- what it is you are trying to do
- and, questions that you might have

Please remember we are not testing you, it is the survey you will be using which is under evaluation. If you get stuck the problem is with the survey not you.

As you fill in the survey I would like you to tell me what you are thinking about as you work. I would like to know about the things you find confusing and the decisions you are making. You do not need to tell me about your private thoughts, I am only interested in your thoughts about completing the survey.

You might have some questions as you fill in the survey. I would like to know what they are but I will not be able to answer them as I do not want to influence the decisions you make.

I would like you to watch this brief video which will demonstrate somebody using the think-aloud technique so you can have a better idea what is expected of you.

Test administrator prompts:

If participant is silent for more than 5 seconds

- “Tell me what you are thinking”
- “Keep talking”
- “What are you thinking now?”

If participant asks “what should I do next?”

- “What are you thinking now?”

To get more detail

- "Can you explain what you meant?"
- “How did you make that decision?”

Appendix R – NRES Committee Yorkshire & the Humber ethical approval confirmation letter

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - Leeds West
Room 002, Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0191 428 3387

23 June 2014

Mr Stuart Gore
Principal Investigator
University of Leeds
School of Healthcare
Leeds
LS2 9JT

Dear Mr Gore

Study title: **A proof of concept study: To design and evaluate a web-based application for detecting self or proxy reports of Traumatic Brain Injury (TBI) exposure over a lifetime through formative usability testing of patients and staff in community drug treatment**
REC reference: **14/YH/0139**
IRAS project ID: **126558**

Thank you for your email of 23 June 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 17 June 2014.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant information sheet (PIS)	1.2	23 June 2014

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering letter on headed paper [REC cover letter for amendments]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		19 September 2013
Participant consent form [Participant Consent Form v1.1]		
Participant information sheet (PIS)	1.2	23 June 2014
Participant information sheet (PIS) [Clinician]		27 March 2014
REC Application Form	3.5	27 March 2014
Research protocol or project proposal [Research Protocol v1.1]		
Summary CV for Chief Investigator (CI)	Meekums	

Summary CV for Chief Investigator (CI)	Gore	
Summary CV for Chief Investigator (CI)	Nolan	

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

14/YH/0139	**Please quote this number on all correspondence**

Yours sincerely

Miss Sarah Grimshaw
REC Manager

E-mail: nrescommittee.yorkandhumber-leedswest@nhs.net

Copy to: *Clare Skinner, University of Leeds*
Dr Bonnie Meekums, University of Leeds
Dr Greg Nolan, University of Leeds

Appendix S – Stakeholder expert reference group recommendations

Design Recommendations	Included (yes/no)	Reason if not included
YES and NO buttons should have different colours (suggestions: green = YES, red = NO)	Yes	
Screen layout should be black writing on white background	Yes	
Avoid bright colours	Yes	
Large fonts	No	No independent user interface reviewer
Customisable screen layout	No	Beyond the functional capability of Snap Mobile Anywhere
Recording TBI history has five time periods, e.g. in the past 3 months, 12 months, 5 years, throughout lifetime and armed forces. Page layout should signify changes between time period	Yes	
Page layout must be kept simple and straightforward	Yes	
Colours engaging	No	No independent user interface reviewer
Clearly differentiate between screen guidance instructions and survey questions	No	No independent user interface reviewer
Screen guidance icon located at the bottom of the screen	No	Beyond technical skill of coder
Icon graphics suggestions e.g. doctor in white coat with stethoscope or brain with a question mark	No	Beyond technical skill of coder
Back and continue buttons located top of screen	No	No independent user interface reviewer

Avoid specific drug colloquialism and use broad descriptive language e.g. drug and/or alcohol use	Yes	
The term 'physical' should prefix the word injury when capturing TBI history to differentiate from emotional injury	Yes	
Avoid computer based technical language	No	No independent user interface reviewer
Clinical language should be retained but explained	No	No independent user interface reviewer
Avoid clinical terminology relating to TBI	No	No independent user interface reviewer
Plain English quick survey questions	No	No independent user interface reviewer
Offer levels of information e.g. basic/detailed relating to TBI	No	Beyond technical skill of coder
Provide brief definition of TBI	Yes	
Remove 'ask the patient' (prompt)	Yes	
Consolidate TBI aetiology e.g. those sustained in a car accident, falls, blasts, those sustained playing sports'	Yes	
Referral guidance to local specialist services via postcode	No	Beyond the functional capability of Snap Mobile Anywhere
Include TBI educational information	Yes	
Open field box for capturing TBI description should include example greyed out e.g. motor vehicle accident	No	Beyond technical skill of coder
Applet feedback area for evaluation	No	Beyond technical skill of coder
Printable TBI test results	Yes	
Inclusion of bio marker for changes in speech and language	No	Beyond the functional capability of Snap Mobile Anywhere

Learning algorithms will be able to replicate this initial speech and language screening process making early detection of mild-moderate TBI more feasible triangulated with lifetime exposure to head injury	No	Beyond the functional capability of Snap Mobile Anywhere
Include survey progression bar	No	Beyond technical skill of coder
Option to skip to specific screens using 'app map'	No	Beyond technical skill of coder