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Article

Service Users' Views and Experiences of Alcohol Relapse Prevention Treatment and Adherence: New Role for Pharmacists?

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Abstract

Aims: To understand service users' views and experiences of alcohol relapse prevention medication, views of a telephone behavioural modification intervention delivered by pharmacists and the use of Contingency Management (CM) to support acamprosate adherence following assisted alcohol withdrawal.
Methods: Four focus groups were conducted within four alcohol treatment and recovery groups across England (UK), with service users with lived experience of alcohol dependence (26 participants). Semi-structured topic guide was used to explore participants' views and experiences of alcohol relapse prevention medication, a telephone behavioural modification medication intervention delivered by pharmacists, and the use of CM to support acamprosate adherence. These were audio-recorded, transcribed verbatim and thematically analysed inductively and deductively.
Results: Four themes were identified: concerns about support and availability of alcohol relapse prevention medication; lack of knowledge and understanding about acamprosate treatment; positive perceptions of acamprosate adherence telephone support from pharmacists; and negative perceptions of CM to support acamprosate adherence. There were misunderstandings about acamprosate's mode of action and strong negative beliefs about CM. However, most were positive about pharmacists' new role to support acamprosate adherence.
Conclusion: This study highlighted challenges service users face to commence alcohol relapse prevention medication. It appears service users could benefit from a pharmacist-led telephone intervention to improve understanding about acamprosate medication, particularly, if delivered in an engaging and motivating way.

INTRODUCTION

Globally, alcohol use was the seventh leading risk factor for both deaths and disability-adjusted life years in 2016, accounting for 2.2% of age-standardized female deaths and 6.8% of age-standardized male deaths (GBD 2016 Alcohol Collaborators, 2018). In spite of this, there has been limited international research exploring why service users face challenges to commence alcohol relapse prevention medication and go on to relapse (Witkiewitz and Marlatt, 2004; Thompson *et al*., 2017). For example, in England, it was estimated that 1.4% of the population were alcohol dependent (Public Health England, 2017) and required pharmacological and or psychosocial intervention. However, in 2019, Public Health England reported only 17.6% of those needing treatment actually received it (Public Health England, 2019), and in 2020, over 60% of those who were treated relapsed to heavy drinking within 6 months (Public Health England, 2020). The period immediately after an assisted alcohol withdrawal can be a vulnerable time, where individuals often struggle to stay abstinent as they try to control their cravings (Maisel *et al*., 2013). This suggests that there is a lack of behavioural modification intervention and medication management support provided to service users to prevent relapse after completing an assisted alcohol withdrawal.

Those experiencing moderate and severe alcohol dependence should be considered for relapse prevention medication, such as acamprosate or oral naltrexone, in combination with or without behavioural modification intervention soon after

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an assisted alcohol withdrawal, and in the UK, this is usually initiated in specialist settings (Roozen *et al*., 2006; Miller *et al*., 2011; National Institute for Health and Care Excellence, 2011; Lingford-Hughes *et al*., 2012). In the UK, it is recommended that the primary health care prescriber, usually the GP, continues the prescription of relapse prevention medication for the remainder of the course and provides monitoring for up to 6 months (National Institute for Health and Care Excellence, 2011). However, high relapse rates indicate that relapse prevention medication is not being prescribed and service users are not receiving behavioural modification intervention as recommended (Goh and Morgan, 2017; NHS England, 2018). In addition, the lack of adherence to these medications will mean people are unlikely to gain their full benefits and instead relapse back to drinking. In the COMBINE study in the USA, which compared pharmacological intervention and placebo with or without behavioural intervention, poor adherence to acamprosate was associated with fewer alcohol abstinent days and an increase in heavy drinking days (Gueorguieva *et al*., 2013). Studies have reported that increasing adherence to alcohol relapse prevention medication is associated with improved alcohol dependence treatment outcomes (Swift *et al*., 2011). Therefore, identifying interventions that support adherence to acamprosate has the potential to improve treatment outcomes for service users.

Studies have investigated whether contingency management (CM), a behavioural modification intervention, could be beneficial as a strategy to reduce drug and alcohol use (Bigelow and Silverman, 1999; Sinclair *et al*., 2011). Findings demonstrate benefits for patients by reinforcing positive behaviour in addiction treatment using incentives, but there is limited understanding for alcohol dependence (Prendergast *et al*., 2006; European Monitoring Centre for Drugs and Drug Addiction, 2016). CM has also been effectively used to support patients' adherence to their medications (Rosen *et al*., 2007; Weaver *et al*., 2014). Thus, there is scope to explore the potential benefits of CM to support adherence to alcohol relapse prevention medications including what type of CM may be acceptable to support acamprosate treatment, e.g. amount and frequency of CM provided.

There is limited research exploring what type of medicines management intervention might be needed and if this could be provided by pharmacists. Medicines management involves supporting patients on the safe and effective use of medicines to gain benefit and reduce potential harm (National Institute for Health and Care Excellence, 2015). Pharmacists routinely provide medicines management interventions to patients experiencing numerous health conditions (National Institute for Health and Care Excellence, 2015). A small number of studies have found that the public and service users were positive about discussing their alcohol use with the pharmacist (Dhital *et al*., 2010; Sheridan *et al*., 2012; Quirk *et al*., 2016; Madden *et al*., 2020); however, this was mainly within the context of an alcohol brief intervention (Dhital *et al*., 2015; Stewart *et al*., 2020). Therefore, it is unknown how service users would respond to an alcohol relapse prevention medication management intervention offered by pharmacists (Peterson, 2007).

This study reports on preliminary work for the UK multi-site randomized controlled trial, Alcohol Dependence and Adherence to Medicine (ADAM, ISRCTN 17083622) to investigate if pharmacists could effectively deliver an acamprosate medication adherence intervention following an assisted alcohol withdrawal with a CM component via the telephone. The term 'service user' is used here rather than 'patient' as it is the nomenclature commonly used in health service research by people likely to be engaged in non-clinic based peer support activities, especially if they had completed an assisted alcohol withdrawal. This study aimed to understand service users' views and experiences of relapse prevention medication, views of a telephone behavioural modification intervention delivered by pharmacists and the use of CM to support acamprosate adherence following an assisted alcohol withdrawal.

MATERIALS AND METHODS

Focus groups were conducted to allow a range and depth of ideas to be explored amongst individuals with a shared experience (Krueger and Casey, 2000; Finch and Lewis, 2009).

Setting

Participants were recruited from alcohol treatment and recovery groups located in four regions of England (London, Wessex, West Midlands and Yorkshire & The Humber) where specialist alcohol services were participating in the ADAM trial.

Sampling and recruitment

Staff from the alcohol treatment and recovery groups at the four regions were informed about the study (by email and telephone) and sent copies of the participant information sheet and consent form to discuss with potential participants. Purposive sampling was used by the staff to identify participants who had completed assisted alcohol withdrawal treatment or were receiving alcohol relapse prevention intervention (pharmacological or psychological). Participants were recruited irrespective of age, gender and ethnicity. Before each focus group, researchers (R.D. and K.D.) obtained written consent from each participant. Participants were reimbursed for their travel and received £20 cash as gratitude for their involvement.

Conducting focus groups

One focus group was conducted at each of the four regions (May to June 2015). Characteristics of participants were gathered using a short questionnaire prior to each focus group. A semi-structured topic guide was developed informed by the trial protocol (ISRCTN 17083622), acamprosate treatment, and CM literature. Topic guide was used to explore participant's experiences and perceptions of taking acamprosate; experience of other types of relapse prevention support, including those from pharmacists; and perceptions and experiences of CM.

Focus groups were conducted in a space known to the participants at each site. Each focus group was facilitated by two members of the research team (R.D., K.D. and T.Pa.). The facilitator who observed the session took notes and at specific points provided brief explanations to participants about aspects of the study and any unfamiliar terminology, including adherence, acamprosate, medication management and CM. A visual summary of the ADAM study, an example of a CM schedule and the actual adherence recording bottles with the electronic Medication Event Monitoring System cap were shown to participants at the start of each focus group to aid

their understanding. Each focus group lasted approximately 1 hour, was audio-recorded and professionally transcribed verbatim.

Group analysis approach

A modified framework analysis was used to organize and thematically analyse the data (Braun and Clarke, 2006; Gale *et al*., 2013). The transcriptions were reread by members of the research team (R.D., K.D., R.C., A.J., K.S. and KW) to familiarize the content and checked for accuracy. Codes were developed inductively from the transcripts as well as deductively from the topic guide by a researcher allocated to analyse a focus group (R.C., A.J., K.S. and K.W.). The codes relating to adherence; acamprosate; medication management; pharmacists and CM were identified after each transcript was coded line by line and no new codes were identified. The codes were then collapsed into broader themes through discussing the process with the research team before finalizing (R.D., K.D., R.C., A.J., K.S. and K.W.). The NVivo (version 11) program (NVivo, 2015) was used to create the codes from the transcripts, collapse into themes and facilitate discussions by sharing files between researchers. Demographic and other characteristics of focus group participants were descriptively analysed.

Ethics and study reporting

The study received local NHS and ethics approval from the West of Scotland Research Ethics Committee (Ref: 15/WS/0048). This manuscript has been prepared following the COREQ Standard for qualitative research (Tong *et al*., 2007).

RESULTS

A total of 26 participants were recruited and one focus group was conducted at each site from the four study regions (Site 1 (London) = 10 participants; Site 2 (West Midlands) = 6; Site 3 (Wessex) = 5 and Site 4 (Yorkshire & The Humber) = 5). The clinics were located in major towns and some within areas of lower levels of deprivation (Ministry of Housing Communities and Local Government, 2019). The average age of participants was 48 years (SD ± 8.36, range 30–69 years) and there were fewer females ($n = 10$, 38%). Of the 26 participants, 13 participants had been prescribed acamprosate previously and others had not. The sample had little ethnic diversity, as most ($n = 23$) described themselves as white British or Irish. Other characteristics of participants are presented in Table 1.

Four themes were identified by analysing responses to questions asked from the topic guide during the focus group: (a) concerns about support and availability of alcohol relapse prevention medication; (b) lack of knowledge and understanding about acamprosate treatment; (c) positive perceptions of acamprosate adherence telephone support from pharmacists and (d) negative perceptions of CM to support acamprosate adherence.

Concerns about support and availability of alcohol relapse prevention medication

Most participants from all groups had attempted to access support following alcohol withdrawal treatment, either from an addiction treatment clinic or through their GP, and most reported negative experiences. Participants expressed GPs were 'unwilling' to prescribe relapse prevention medication and appeared instead to expect the alcohol treatment clinic to do so. Participants also expressed they were treated 'unfairly' compared to others when accessing treatment, i.e. that some were offered relapse prevention medication while others were not, which indicates there may be variation in the way alcohol support is provided from addiction clinics and GPs across England. Participants from all groups reported there was a general lack of professional support available to them following alcohol withdrawal and as a result had struggled to remain alcohol free. Participants reported they had not been offered relapse prevention medication following withdrawal treatment from addiction treatment services or GP surgeries:

> 'I was never offered . . . there was never a discussion about anything, I done my five-day detox, off you go, see you later; never heard nothing from the GP, so obviously was back on the drink then'. (S1, F2 = Site 1, Female participant 2)

Past experiences of accessing support appeared to have affected most participants' expectation of the type of support they might receive. Participants from each focus group reported accessing alternative types of support, other than health professionals, such as peer groups and fellowships (AA and SMART recovery). They also found it helpful having family and friends support during their alcohol withdrawal and relapse prevention treatment:

> 'Well, it's been a massive thing for me . . . I've been through the cycle of relapse, detox, relapse, detox and the stumbling block was always . . . having support after I came out of detox and this time going to the SMART groups and being part of what's going on has helped'. (S4, M2 = Site 4, Male participant 2)

Lack of knowledge and understanding about acamprosate treatment

A range of views were expressed within this theme. Half the study participants had been prescribed acamprosate and each focus group comprised of participants with previous experience of taking acamprosate. Most participants from all groups indicated acamprosate could be a beneficial treatment or had been useful to reduce their cravings. Participants from each group who had been prescribed acamprosate expressed they were able to remain abstinent for longer:

> 'I haven't touched nothing for six months . . . it stopped the cravings . . . it's working'. (S3, M3)

However, participants from each group appeared unsure whether acamprosate could help them. This included doubts about the medication's effectiveness and fear of relapse whilst taking the medication. One participant (from S2, M1) highlighted that information about acamprosate should be widely available so service users can make informed decisions about their treatment. There appeared to be a general lack of understanding about acamprosate treatment. Participants from all groups appeared to be influenced by experiences and opinions of peers when making decisions about their treatment:

Table 1. Characteristics of focus group participants (values are numbers (%) unless stated otherwise)

Characteristics	Focus group Site 1 ($n=10$)	Focus group Site 2 ($n=6$)	Focus group Site 3 ($n=5$)	Focus group Site 4 ($n=5$)	Total ($n=26$)
Age years: mean (SD), range	50 (7.91), 35–60[a]	45 (2.80), 42–50	45 (9.26), 30–54	52 (12.17), 35–69	48 (8.36), 30–69
Gender					
Female	5 (50)	2 (33)	1(20)	2 (40)	10 (38)
Male	5 (50)	4 (67)	4 (80)	3 (60)	16 (62)
Ethnicity					
Asian/Asian British	0 (0)	1(17)	0 (0)	0 (0)	1(4)
Black/African/-Caribbean/Black British	2 (20)	0 (0)	0 (0)	0 (0)	2 (8)
Mixed/multiple ethnicity	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
White British	7 (70)	4 (67)	5 (100)	5 (100)	21 (81)
White Irish	1 (10)	1 (17)	0 (0)	0 (0)	2 (7)
Currently receiving relapse prevention treatment (psychosocial and/or pharmaceutical) for alcohol dependence					
Yes	4 (40)	5 (85)	3 (60)	3 (60)	15 (58)
No	6 (60)	1 (17)	2 (40)	2 (40)	11 (42)
Ever been prescribed acamprosate					
Yes	2 (20)	5 (83)	4 (80)	2 (40)	13 (50)[b]
No	8 (80)	1 (17)	1 (20)	3 (60)	13 (50)

Site 1 (London); Site 2 (West Midlands); Site 3 (Wessex) and Site 4 (Yorkshire & Humber). [a]Missing data for one participant. [b]Of the total 13 participants who were prescribed acamprosate: 6 were prescribed during 2015; 4 in 2014; 1 in 2013; 1 in 2012 and 1 during 2003/2004.

> 'Some said it didn't work for them . . . it may make you physically sick, some people said it made them worse'. (S1, F1)

Participants from all groups expressed difficulties with taking acamprosate, especially with having to remember to take two tablets three times a day. This created further barriers for a few (from S1 and S4) who were taking additional medicines alongside acamprosate. Few expressed challenges of a stigmatizing work culture, for example trying to take alcohol treatment tablets discreetly during breaks (S4, F1). Most participants had negative experiences and held negative views about taking their treatment which was related to the medication administration burden:

> 'Sometimes I miss a dose just because I'm busy . . . I can completely forget about it and it's usually my afternoon one, the middle of the day. I'm taking six tablets a day and you do that for a long period of time, you do get resentful of the medication, of the actual taking of the tablet'. (S2, M2)

Participants from all groups appeared to lack knowledge about acamprosate's side effects. Few had experienced gastrointestinal problems and nausea and were unsure about interactions between acamprosate and other medications, such as antidepressants. It appeared participants may not have received this information after their alcohol withdrawal treatment and were unsure from whom and where to seek help.

Positive perceptions of acamprosate adherence telephone support from pharmacists

When participants were asked if they thought pharmacists could help resolve their possible concerns about acamprosate, through a telephone support service, participants from all focus groups expressed positive views. Few expressed they had received limited support in the past and thought having a pharmacist to discuss acamprosate on the telephone could have helped them engage with their treatment for longer:

> '. . . I did a whole detox, followed by the acamprosate at home. I think a phone call once a week from somebody who knew what they were talking about and could ask me how things were going; I might have stuck with them longer . . . There was no support from my GP, he just gave me them [acamprosate] and said they'll help with the cravings, see you in a month'. (S4, F1)

When asked how the pharmacist telephone support could be delivered, most suggested intervention calls should be structured, take place regularly, vary in length depending on need and be service user led. There was good agreement, from all focus groups, that the pharmacist telephone support service should include these specific features. Participants from all groups also expressed more support should be available during difficult times, particularly soon after alcohol withdrawal treatment.

However, participants from each group also expressed whether the telephone intervention could be impersonal, therefore not helpful and preferred face-to-face contact. Other general views about pharmacists were also expressed during all focus groups. Most participants reported visiting community pharmacies to collect their medications and interacting with members of the pharmacy team about their health. Participants from each group also reported they felt supported by their community pharmacists to take their medications and learn about interactions.

Though participants from all groups were generally positive about pharmacists providing acamprosate adherence telephone support, most were equally uncertain about how knowledgeable and skilled pharmacists were for this new role. Most participants felt pharmacists not only had to be knowledgeable about medicines but also have good communication skills:

> 'You need to have the expertise about the medication . . . show that bit of empathy . . . have some understanding of what you're going through, to be able to keep you going'. (S4, F2)

Most participants from all groups expressed communication skills were important, especially to build rapport and understand the patient's experience. However, participants from all groups were concerned pharmacists may lack specialist knowledge about alcohol problems and questioned whether it was appropriate for them to take on this new role:

> 'I think you're asking a lot of the pharmacist. It's a very special subject and if you start asking them to do this, another group will start asking them to do the same thing for another treatment . . . and all of a sudden, they're not pharmacists any more, they're psychiatrists'. (S4, M1)

Negative perceptions of CM to support acamprosate adherence

After presenting an example CM schedule to participants, which comprised of a short table listing the number of pharmacist telephone interventions completed over several weeks with a suggested CM value, strong and negative reactions were expressed by participants from all groups. Most participants were strongly opposed to receiving a 'reward' for engaging in treatment. This component of the telephone intervention created the strongest and most unanimous reaction by participants across all groups:

> 'Bribery . . . it goes against my ethics.' (S3, M1)

Most participants from all groups thought CM was unlikely to work, and people would use the incentive to purchase alcohol. It was not considered a good use of resources and few thought being prescribed acamprosate was enough to support their treatment (S4). Some expressed concerns about CM, equating it to reinforcing addictive behaviour:

> 'It's the reward thing. In addiction, you are rewarding yourself by having your drink, or having your drugs. You're rewarding your thoughts by doing that and that's exactly what this is doing . . . '. (S4, F2)

However, participants from each group also recognized the value of 'rewarding' someone in recovery. Interestingly, participants from each group who had previously expressed negative thoughts also held positive views about CM. These participants suggested the CM incentive should be practical, relevant to their needs and staggered during the trial intervention. Alternatives to cash were suggested by a few, which included an experience-based activity with members of their family. Participants wanted the CM to not only impact them financially but also personally and make them feel valued:

> '. . . you can reward yourself in other ways . . . if you complete this with the appropriate phone calls. I think there should be something . . . to say, you've bloody done it . . . '. (S4, F1).

DISCUSSION

Participants expressed a range of views on alcohol relapse prevention medication from the focus groups, as presented in the four themes identified. Concerns were expressed about the availability and disparity of support; there was a lack of understanding and confusion about acamprosate treatment; strong negative beliefs about the concept of CM were voiced; however, most were generally positive about the new role for pharmacists to support acamprosate adherence through a telephone intervention. A purposive sample of 26 participants identified by staff from alcohol treatment and recovery groups had all engaged with alcohol treatment services, half had at some point been prescribed acamprosate and over half (58%) were currently receiving psychosocial and/or pharmacological treatment for alcohol relapse prevention. These findings were context specific and informed by participants' lived experiences of past or current alcohol dependence treatment, which adds to the study's strength.

When exploring whether pharmacists could support patients to take alcohol relapse prevention medication, a range of views were expressed. Some felt there was already enough support in place from clinic keyworkers and GPs, though these experiences were not supported with specific accounts of receiving higher frequency of contact from clinic workers. This suggests a number of things that participants were satisfied with the service they received, may have experienced low levels of alcohol relapse problems or were unaware about the benefits of additional support. Particularly, as participants also reported difficulties with remembering to take their medicines, uncertainty of side effects, medication's effects on their cravings and relying on peers for information, which all suggests a need for additional support including from pharmacists. However, for pharmacists' support to be useful, participants wanted pharmacists to have good communication skills and be empathetic to their situation. Additionally, some participants favouring face-to-face communication rather than via telephone. Currently, there is no formal training focusing on alcohol relapse prevention for pharmacists; therefore, a bespoke training was designed for ADAM trial pharmacists. This suggests that pharmacists are likely to require training to communicate knowledge about alcohol relapse prevention medication in an engaging way, especially to optimize treatment benefits.

Some participants reported negative experiences for their alcohol dependence, receiving little or no after-care following an assisted alcohol withdrawal from the clinic. There were reports of GPs 'refusing' to prescribe acamprosate following discharge; in contrast to NICE recommendations that acamprosate should be offered for minimum 6 months (National Institute for Health and Care Excellence, 2011). Participants identified the stigma associated with alcohol dependence and felt judged by society. Participants from all four groups reported disparity in the way care was delivered, with some receiving more support than others. This highlights a need to develop a more equitable, accessible and joined up alcohol support service within primary and secondary healthcare (Gilburt *et al.*, 2015), involving a range of practitioners including pharmacists. Particularly as negative experiences may have affected participants' trust toward support for alcohol problems and explain why participants held negative views about CM, with some considering it to be a 'bribe', rather than viewing this as an intervention to engage

people in acamprosate treatment to aid their recovery. These negative perceptions may dissuade people from engaging in acamprosate treatment (Shaw *et al*., 1978) and explain the high relapse rate for this patient group. Despite NICE's recommendations (National Institute for Health and Care Excellence, 2011), study participants appeared to receive little or no support soon after assisted alcohol withdrawal treatment, which confirmed similar findings from the Clinical Practice Datalink study where the medium duration of acamprosate treatment was only 2 months for a population of 39,980 diagnosed with alcohol dependence (Thompson *et al*., 2017), which is low compared to the recommended minimum 6-month treatment duration. Our study findings suggest that participants experienced a lack of continuity of care following an assisted alcohol withdrawal from clinics across England. Factors that may have contributed to this need to be examined, especially to improve future service design and remove barriers to engagement.

However, findings from this focus group study provide new insights on how CM could be made more engaging for participants, for example participants preferred the term 'treatment award' when describing CM; which meant you were 'awarded' for your engagement with the treatment rather than 'rewarded'; which participants reported was akin to a 'bribe'. In addition, engaging with acamprosate treatment was viewed as a personal goal. This led to CM being renamed 'personal achievement award' for the ADAM trial following participants' preference. Participants wanted to speak with the pharmacist not only when things were going well with their acamprosate treatment, during the regular telephone calls, but importantly when they were struggling and would benefit from discussing this with the pharmacist. Participants also expressed it was important to receive CM for engaging in the pharmacist telephone intervention rather than completing the prescribed acamprosate course. Participants did not want to feel penalized for not taking their medications but wanted support to adhere to their treatment. This highlighted the value of undertaking preliminary qualitative research to inform the 'look and feel' of health interventions to engage participants. Participants' views and perceptions were informed by their experience of alcohol dependence and receiving support. We should note only 17.6% of those with alcohol dependence receive treatment in England (Public Health England, 2019); therefore, our focus group sample comprises a 'minority voice', i.e. who received treatment for alcohol dependence.

The group analysis approach allowed thoughts to be regularly shared and guided by the focus group lead (RD) with alcohol research and addiction pharmacist experience. The focus groups were conducted with participants from four different regions across England, thus allowing a breadth of experiences to be captured, adding rigour to the analysis process and strengthened the findings (Mays and Pope, 1995).

Limitations

Focus group participants shared challenging and sometimes difficult experiences with the group. In future, one-to-one interviews may be more appropriate for some individuals, especially to capture in-depth experiences more sensitively (Rubin and Rubin, 2012). The focus group data were collected during 2015; however, no similar study was identified since data collection making the findings relevant for future research and clinical practice.

CONCLUSION

This focus group study allowed new insights and perceptions on the impact of lack of support and provision of acamprosate prescribing experienced by participants to be better understood. In addition, participants lacked understanding about acamprosate's mode of action and could therefore benefit from pharmacist's knowledge to support adherence to acamprosate and thus inform the content of the ADAM trial.

DATA AVAILABILITY STATEMENT

Study protocols and datasets are available from the corresponding author on reasonable request.

AUTHORS' CONTRIBUTIONS

E.D., K.D., C.D., A.L.-H., J.M., T.P., J.Si., J.St., J.W. and C.W. developed the original concept of the study and acquired the research funding. R.D. developed and finalized the focus group study design, led the analysis and wrote the first draft of this paper. R.C., R.D. and K.W. analysed the focus group data. R.C., R.D., K.D., K.W. and all authors commented on the final preparation of this paper. All authors have read and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

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