Substance misuse intervention research in remote Indigenous Australian communities since the NHMRC 'Roadmap'

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Abstract

Objective: Describe program theories of substance misuse interventions with Aboriginal and Torres Strait Islander (Indigenous) Australians funded by the National Health and Medical Research Council (NHMRC) since the 'Roadmap' for Indigenous health.

Methods: Projects funded 2003-2013 were categorised by intervention strategies. Realist concepts informed the program theory: intended resources and responses; influence of context on outcomes; explicit and implicit program assumptions.

Results: Seven interventions were included. Three randomised controlled trials targeted tobacco using psychosocial interventions in primary health centres using the program theory: "Local Indigenous health workers extend and sustain the effects of conventional clinical brief intervention by engendering social and cultural resources". Four pragmatic trials of multiple-component, community-based interventions using controlled, semi-controlled or before-and-after designs used the program theory: "Discrete intervention components targeting locally defined substance misuse issues will activate latent capacities to create an environment that favours cessation." Publications did not report clear effect, implementation fidelity or explicit mechanisms affecting participant thinking.

Conclusions: Rigorous intervention designs built on 'Roadmap' principles neither reduced substance use in the populations studied nor identified transferable mechanisms for behaviour change.

Implications for public health: Substance misuse impacts among Indigenous Australians remain severe. Theoretical mechanisms of behaviour change may improve intervention design.

Key words: program evaluation, substance abuse, indigenous population, intervention study

Behavioural change intervention studies to reduce substance misuse among Australia's Aboriginal and Torres Strait Islander (Indigenous) populations have seldom demonstrated clear effects.[1,2] The lack of demonstrated effect is not limited to Indigenous health intervention research. For example, less than half all health intervention studies funded by Australia's National Health and Medical Research Council (NHMRC) from 2003 to 2007 produced convincing evidence of intended effects.[3] For Australia's Indigenous peoples, evidence from population-level intervention studies is essential to meet the national commitment to close the health gap with improved policy and evidence-based service delivery,[4,5] yet the bulk of research outputs have been descriptive.[6]

In Australia's remote Indigenous communities, the overall health gap compared to other Australians is extreme and persistent,[20] with a heavy burden of chronic disease and substance misuse.[21,22] A Strategic Framework for Improving Aboriginal and Torres Strait Islander Health Through Research (NHMRC 'Roadmap')[23] and its consultation document[24] were published in 2002. The documents consolidated the demands of stakeholders in Indigenous health for ownership and partnership in research to achieve direct health benefits. Since 2002, the NHMRC has committed up to 5% of its annual budget to Australian Indigenous health research.[25]

For health behaviour change generally, innovative, practical and pragmatic research approaches have been recommended to enhance the quality and transferability of complex interventions.[2,7,8] Theoretically informed intervention programs are also advocated because the evaluation of complex behavioural interventions often requires nuanced insights into processes of change within complex systems operating in real-world settings.[5,6,9-11] For Indigenous community settings, to date, no review has been published that describes or synthesises the theoretical underpinnings, i.e. program theories, of health intervention research.

We examined the published outputs of NHMRC funded research project grants from 2003-2013 that implemented or evaluated interventions directly targeting substance misuse in remote Australian Indigenous communities. We examined the available evidence through the lens of scientific realism. This approach has been increasingly applied

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to theorise how and why complex health and social interventions affect the reasoning of behaviour change program participants,[12,13] and to strengthen translation of research into policy and practice.[14] A *program theory* of an intervention consists of the set of implicit or explicit assumptions about how participants will respond to the array of resources an intervention may precipitate.[16] Scientific realism makes the unique contribution of conceptualising intervention processes that a *program theory* implies as clusters of *mechanism, context* and *outcome. Mechanisms* are conceptualised as theoretically plausible responses of program participants to *resources* that arise from an intervention program.[11] In realist terms, *resources* are seen not just as discrete and tangible intervention components, but also intangible, intended or unintended elements that confront or become available to participants in the population for whom the intervention is intended. In this way, the realist *mechanism* provides an approach to explicitly theorising and elucidating underlying processes that could explain change.

A further important contribution of scientific realism is in conceptualising participant responses to resources as being mediated by *context*; which may not always be comprehensively described in an intervention design, or even be predictable.[11,15] However, realists seek credible evidence about how intervention programs exert their effects in varying *contexts.* Systematic examination of theorised mechanisms in relation to empirical outcomes in different contexts informs further theories about the transferable components of intervention programs and the contextual conditions that enable intended mechanisms to be activated to achieve intended *outcomes*.[16,17] Consistent with the initial steps recommended for a *realist synthesis*,[18,19] this review of substance misuse interventions in remote Australian Indigenous communities categorises program theories of the included projects in realist terms.

Methods

Identifying research projects for inclusion and articles published

The outcomes of funding rounds reported on the NHMRC website were searched for project grants that commenced from January 2003 and during the decade up to 2013 following publication of the first NHMRC 'Roadmap'.[23] Projects implementing a community-level intervention targeting substance misuse, with a principal focus on Indigenous populations in rural and remote areas were selected by examining abstracts from key publications. Projects funded after December 2013 were not included as they would have had insufficient time to implement and evaluate an intervention study at time of synthesis and writing of this review. Status as 'current' or 'complete', and (if available) summary of outcomes were obtained from the NHMRC National Register of Public Health Research.[22]

Overview of review methods

The review method involved the following steps:

1. Relevant peer-reviewed publications were sought for review in PubMed, Scopus, Google Scholar and the 'Health Infonet' website.[20] A systematic search used primary chief investigator name and topic or key words from the grant title as search terms. Citations included in the reference lists of articles reporting eligible studies were manually reviewed to identify additional publications. Only peer-reviewed literature was included. Accordingly, grey literature, evaluation reports, theses, conference proceedings, posters, tangible resources developed for the intervention, social marketing materials and magazine articles were not included.
2. For each research project study designs, interventions and intended outcomes were summarised.
3. How each program was intended to work to achieve specific outcomes was examined, i.e. the implicit or explicit mechanisms (potential resources and responses) within a program theory.
4. Program theories underlying each study's design were outlined by speculating on the resources program designers intended their strategies to produce, and the anticipated response to the program by participants and other stakeholders.
5. Data extraction and analysis

To manage the information, publication outputs for each project were assigned to case nodes according to project grant in NVivo™11.

First, general descriptive information was extracted (VG) for each project by reviewing publications relating to each study to identify:

explicitly stated aims of the study

- substance or activity targeted
- number of participants
- number of sites
- length of study (years)
- total funding
- type of study design
- intervention strategies
- measured or observed outcomes
- any process evaluation design.

Second, the selected articles were read in detail (VG and AC) and searched for subthemes (VG) in the following categories:

Theory

- theoretical framework: any specification of a theoretical basis for the strategy
- mode of delivery: participatory, brief intervention at the clinic, multiple component, action research
- practitioners: agents responsible for delivering the intervention components at the community level (doctors, local health workers, research staff, other professional)
- participants: who received the intervention resources and at what level in the community (i.e. residents, service provider or community organisation).

Outcomes:

- main outcomes: reported participant responses or main outcome measures
- unintended outcomes: unanticipated participant or stakeholder responses
- broad indication of fidelity of intervention: components implemented as designed designated as 'most', 'some' or 'few'.

Contextual factors that influenced implementation fidelity or uptake:

- observations published by investigators in their evaluation of success of intervention components including feasibility of design, staffing, cultural or political factors influencing implementation or participant/stakeholder response.

Speculating on intended mechanisms

Consistent with the realist concept of *mechanism,* we searched the publications for any evidence of the hoped-for change in participant thinking in response to the resources that were intended to be mobilised by the intervention strategy.[21] Distinct from the tangible intervention resources,[13] we searched for evidence of any changes in the environment, structure or relationships arising from intervention strategies. These are

often not explicit in the aims or design of the intervention, but rooted more deeply in the assumptions (implicit or explicit) made by the program designers about how the program *should* work and in their speculations about any unintended resources imparted by an intervention.

Key assumptions and articulating the program theories they imply

Key assumptions underpinning program theories for individual studies were derived by considering the aims of the intervention in relation to the actual outcomes and observations reported combined with methodological assumptions found in the literature for the study designs employed. A program theory was articulated for projects in statements prepared, discussed and agreed by the authors. Statements summarised our speculations for how and why a particular intervention strategy was intended to change a given behaviour in participants.

Findings

Research programs and projects included

A total of 33 peer-reviewed publications arising from seven intervention studies funded by eight NHMRC funded project grants awarded between January 2003 and December 2013 were included in this review. Most of the project grants were listed as 'current' on the NHMRC National Register of Public Health Research (accessed February 2016). Together they represented a total budget of over five million dollars for 30 project-years. Table 1 provides an overview of the projects, their design, outcome measures and citations to published articles.

On the basis of their physical focal point, studies were categorised as 'Clinic-based' or 'Community-focused'. For each group, explicitly stated elements of the intervention strategies and the implied theoretical components are summarised in Tables 2a and b and are discussed below.

a) Clinic-based programs – brief intervention at the clinic augmented by social support

Three studies targeted tobacco with intervention strategies primarily focused on the local primary health centre (the 'clinic') combining evidence-based behavioural counselling and social support components. All used a randomised controlled trial (RCT) design. The interventions were designed to support tobacco cessation or to prevent exposure of infants to second hand tobacco smoke through cessation by parents and household members (projects labelled A1, A2 and A3 in Table 2a). In each study, participating clinic patients, randomised to the intervention group, received brief intervention different to usual care, as well as nicotine replacement therapy (NRT) where appropriate. A social support component was delivered by local health workers either at the clinic, in homes, or by phone. The main outcome measures were current tobacco use at follow-up, time to last cigarette, urinary cotinine concentration and admission to hospital for acute respiratory events in infants.

Outcomes in context: Summarised and highlighted in Table 2a, none of the evaluations of implementation reported statistically significant effects attributable to the intervention.[22-24] However, meta-analysis of the pooled data from two (A1 and A2) found a significant effect of intensive health worker support on tobacco cessation.[24] Program A1 established that pregnant women who had already quit smoking independently of an intervention remained non-smokers at the end of their pregnancy.[25] This cohort also contributed data for measurement studies of the Fagerström Test for Nicotine Dependence and self-reported tobacco use validated with urinary cotinine concentrations among pregnant Indigenous women.[26,27] Project A3 found that infants of breastfeeding mothers had higher exposure to tobacco smoke, despite successful and willing management of smoke-free homes and cars.[30,31] Encouraging behaviours reported qualitatively but not captured objectively by the designed outcome

Table 1: Overview of project grants funded by the NHMRC 2003-2013 that implemented and or evaluated an intervention at the remote community level targeting substance misuse.

Year	Grant title	Life of grant	Intervention name	Type of intervention	Study design, outcome measures	No. sites	Articles
2003	Impact of a multi-intervention anti-tobacco strategy in 8 Indigenous communities	5	The North Queensland Tobacco Project	Pragmatic, multiple components and stakeholders	Cohort survey of tobacco use, intentions to quit; RCT and process evaluation	8	30, 37
2005	Helping Indigenous women to stop smoking during pregnancy	2	Tilly's Tracks	Clinical brief intervention plus social support from a health worker	Tobacco use, urinary cotinine; implementation; RCT and fidelity of sample of implementers	2	23, 25, 47
2007	Community action for smoking cessation in remote Aboriginal communities	5	The Top End Tobacco Project	Pragmatic, multiple components	Before and after cohort survey in three locations; prevalence, patterns of tobacco use and sales data; multiple baseline study and process evaluation	3	38-41, 48-56
2008	Years 4 & 5 of an RCT psychosocial tobacco intervention in urban pregnant Indigenous women	2	Tilly's Tracks	Clinical brief intervention plus social support from a health worker	RCT tobacco use, urinary cotinine; process evaluation	2	23, 25
2008	Randomised Controlled Trial of an intensive smoking cessation intervention in Kimberley Aboriginal primary health clinic setting	3	Be Our Ally Beat Smoking (BOABS)	Clinical brief intervention plus social support from a health worker	Tobacco use, urinary cotinine; meta-analysis with Tilly's Tracks data; RCT and process evaluation	2	24, 31, 57
2009	Randomised controlled trial of a family tobacco control program to reduce respiratory illness in Indigenous infants	5	Healthy Starts (in Australia)	Clinical brief intervention plus social support from a health worker	Acute respiratory events, urinary cotinine; qualitative interview; RCT and process evaluation	2	22, 28, 29, 33, 34, 58
2010	Indigenous action to reduce harms associated with heavy cannabis use in Cape York	3	The Cape York Cannabis Project	Pragmatic, multiple components and stakeholders	Before and after cohort survey in three locations; prevalence, patterns of cannabis use; multiple baseline study and process evaluation	3	59, 60
2013	Intervention trial to reduce alcohol related harms among high risk young Indigenous Australians	2	Beat da Binge	Community-initiated diversionary strategies	Before and after survey of alcohol consumption patterns; process evaluation	1	35, 36

measures were high willingness to participate in A2[23,] A3[28,29] and B2[30] and the value of local ownership, flexibility and cultural safety in A1.[31]

It appeared that in all contexts, participants' home environments and local relationships exerted powerful influences that were difficult for intervention components to influence, even with the use of local trained health workers and face-to-face counselling or home visits.[25,31,32] The challenges of isolation, the absence of a local project manager to maintain project impetus,[31] staff turn-over[30,31] and significant investment in retraining health workers,[31] and low fidelity of health worker delivered components[23,30,31] were variously reported. For example, two of the psychosocial interventions (A1 and A2) were challenged by high staff turn-over and the effort required for retraining, together with other barriers to health workers engaging with participants.[25,31] Adaptations to the original study designs included altered follow-up schedules due to participant attrition[23] and extending the time allocated for recruitment due to underpowered samples and deviation from original recruitment criteria.[31] Possible contamination of control with intervention was observed in study A1,[23] leading the researchers to recommend the use of an alternative design, i.e. a cluster RCT. Project A2 reported "*cultural obligations that restricted access of Aboriginal researchers to some community members*", for example jealousy or family relationships that precluded offering advice.[31]

Program theory, underlying assumptions: The clinical components of these interventions have an independent evidence base, mostly derived from non-Indigenous contexts. The underlying program theory acknowledging the emphasis on complementary social support components of the interventions could be framed as:

> *Local Indigenous health workers augment, extend and sustain the effects of conventional clinical brief intervention by engendering social and cultural resources.*

Summarised and highlighted in Table 2a under the heading 'How and why?' are the types of resources and responses intended by the intervention. The clinical components offer potential resources such as authoritative information and guidance as well as relief from withdrawal symptoms. This assumes that participants and local Indigenous health workers will engage with a western biomedical model of harm to some degree, and that they can or will prioritise the intervention outside the clinic setting. Participant time taken to receive health advice could potentially support self-reflexivity at the individual or family levels and help participants to feel better able to employ strategies such as setting goals and limits. The intention of social support was to help alleviate cue exposure and reduce stress during nicotine withdrawal. Providing structure, encouragement and information about smoking's harms aimed to create environments that would favour sustained cessation. Assumptions seemed to be made that social support was relevant to cessation, about who can increase this resource and how this occurs. A key assumption deduced by aligning intentions with the actual outcomes in context in Table 2a seems to be that local health workers have capacities such as knowledge, relationships or local authority to provide the support that might augment evidence-based clinical intervention. The mechanisms by which this was intended to happen were not specified in any of the published outputs. However, mechanisms were implied in some of the strategies used to support health workers to deliver their components, such as employing female workers to work with pregnant women[23] and using culturally appropriate resources and discourse as well as providing training.[33,34]

(b) Community-focused programs - multi-component, multi-site community level interventions and participatory action research

Four community-focused intervention studies targeted tobacco (n=2), cannabis (n=1) and alcohol (n=1). One of the tobacco studies was

Table 2a: Program theories of the psycho-social, clinic-based interventions within a controlled study design (group a).

Intervention study	What was the program supposed to do?		Outcomes in context	
	Intended outcome/Aims	Detailed strategies	Observed outcome as reported	Influence of context reported in evaluations
A1	Tobacco cessation among pregnant women	• Evidence-based clinical brief intervention including behavioural approaches and NRT • Social support components: – Home visits or intensive counselling with local health workers or Aboriginal researchers as complementary – Local Indigenous health workers received training for their component	Not significant; significant in meta-analysis with BOABS	• High willingness to participate among pregnant women • High level of control of smoke-free cars and homes with infants • Some components implemented with fidelity, few health worker components implemented as designed • High staff turnover and high researcher input • Barriers to health worker engagement reported in some instances • Recruitment and/or retention was challenging
A2	Cessation or intentions to quit		Double usual care, not significant; significant in meta-analysis with Tilly's tracks	
A3	Parental and family behaviours that minimize exposure of infants to second-hand smoke, including cessation		Not significant; self-reported high control of smoke-free spaces; higher exposure in the infants of breastfeeding mothers	

Program theory/ies	How and why?		Assumptions
	Kinds of resources intended	Intended responses	
Local Indigenous health workers augment, extend and sustain the effects of conventional clinical brief intervention by engendering social and cultural resources	• Biomedical relief; clinical authority • Cultural safety and relevance, including gender-specific health worker support • Structure; time out • Self-reflexivity • Shared and culturally relevant understanding of harms; or goals among family members	• Trust medical authority • Motivated to abstain • Reaching out to family for support or offering support • Reinforced and informed concern for infant • Enhanced capacity to set goals; effect changes or enforce limits	• Brief intervention strategies in health clinics serving Indigenous people will work in a similar way as elsewhere; possibly entailing respect for clinical authority and a western-European conception of risk and deleterious consequence to influence behaviour • Local health workers hold latent capacities and knowledge that can fulfil needs for culturally appropriate strategies • Health workers have authority or cultural mandate is valid to encourage behaviour change, educate or assert role with fellow community members; specifically, the capacity or influence to: – interpret and implement intervention concepts – can and will prioritise the intervention outside the clinic – deliver an externally driven intervention, with limited training and management

a cluster RCT and the other used a multiple baseline design (MBL). The intervention to address cannabis use also employed a MBL. The intervention targeting binge drinking among youth featured community-based participatory research (CBPR) in a single community with no experimental control and a pre-post study design, plus process evaluation (compared in Table 2b).

All four projects in this category aimed to use multiple components implemented at various levels of the community through action research. Three of the community-focused interventions (B1, B2 and B3) used a pragmatic, multiple-component approach to whole-of-community interventions. Evidence-based intervention components (e.g. motivational enhancement therapy to enhance readiness to change) were brought to bear combined with local strategies stimulated by the intervention or during consultation (e.g. raising awareness in schools; implementing local policies in safety plans or changed workplace practices; local diversionary strategies). The cluster RCT tobacco intervention (B1) delivered a suite of pre-planned evidence-based components, several of which were highly structured strategies delivered by professional service providers (e.g. clinic-based interventions or embedding anti-tobacco content into school curriculum). The interventions in the MBL studies (B2 and B3) incorporated loosely defined intervention components at the outset. In the MBL studies, baseline prevalence surveys were conducted and feedback of study results immediately followed with this viewed as a potential strategy to stimulate local concern and locally inspired intervention strategies.

The intervention targeting binge drinking among youth (B4) was reportedly initiated by local community members, with researchers participating as invited partners. The project was described as having evolved from local awareness raising and diversionary strategies into a campaign for youth advocacy, leadership and training.[35] The study design was a straightforward before-and-after evaluation by opportunistic survey, a planned cohort study not being feasible in the circumstances under which the project progressed.[36] A four stage approach was used in which local Aboriginal knowledge was integrated with the evidence base.[36]

Table 2b: Multi-component at multiple levels of the community pragmatic action research (group b).

Intervention study	What was the program supposed to do?		Outcomes in context	
	Intended outcome/Aims	Detailed strategies	Observed outcome as reported	Influence of context reported in evaluations
		Multi-level, multi-component, action research, community consultation / engagement; data feedback, local social and evidence-based components		• Some or most planned components partially implemented but few with high fidelity • Low uptake of opportunities for locally driven intervention strategies (B1,2,4) • Participants in pre-contemplation (B1-2) • High awareness, resentment for financial burden, high prevalence (B2-3) • Retailers very engaged (B2) • Clinic services not always fully engaged in tobacco reduction strategies • Local health workers sometimes lacking support • Existing anti-tobacco resources sometimes limited to the clinic and not in the community as such (B2) • Siloing, opportunism observed among services • Trust, sense of ownership endorsed as essential participation (B1,2,4)
B1	Tobacco cessation	Pragmatic, cluster RCT; Social, clinical and policy components pre-planned with stakeholders and services	Significant reduction in current use and more people thinking about quitting not definitively attributable to interventions	
B2	Tobacco cessation	Pragmatic, multiple baseline study; Minimal pre-planned, evidence-based components; Feedback local data, repeated visits; information, brief intervention, policy advocacy	Non-significant qualitative impact; policy initiatives, e.g. tobacco-free spaces	
B3	Reduce heavy and dependent cannabis use		Decline in use > hypothesized; process evaluation incomplete at time of publishing	
B4	Reduced youth binge drinking; enhanced local youth engaged in locally initiated activities	Participatory, pre-post survey; participant-initiated diversionary strategies, academic and other partners. Focused on social belonging, local ownership	Significant decline not definitively attributable to intervention; High community engagement	

Program theory/ies	How and why?		Assumptions
	Kinds of resources intended	Intended responses	
• A suite of evidence-based interventions across a community will change attitudes and produce a more favourable environment for cessation • Local data and relevant information will stimulate and or support local agency to act on a recognised issue • Community owned and initiated diversionary strategies can reduce youth binge drinking by providing social resources that are more highly valued than the effects of alcohol	• Enabling environments or attitudes for cessation • Community-wide attitudinal or awareness changes • Issue is brought out for discussion - outsiders neutral listeners • Translation between community needs and policy • Fun and belonging • Raised awareness, reflexivity and self-regulation • Genuine control and ownership	• Prioritise quitting, desire to quit • Community resolve • Issue confirmed, new perspective of severity • Reflection, perceive choice and consequences, regulate behaviours • Desire to participate greater than desire to consume • Persistence, purposeful participation in cyclical change processes	• Partnerships create trust, are synergistic • Local partners confer cultural specificity • Strategies initiated locally target latent mechanisms • Adequate stakeholder capacity and will to uphold mandate • Local stakeholders will prioritise issue and strategies which they identified as high need

As invited partners, researchers' intended roles, in addition to providing specialist knowledge and skills for monitoring and evaluation, appear to have been to reinforce partnerships, advocate for the project to policy makers and funding bodies, and to supply or interpret information from the literature or evidence base.

Outcomes in context: Summarised and highlighted in Table 2b, some moderate impacts were observed for all of these studies with implementation fidelity mediated by similar processes across the four. The tobacco-control cluster RCT (B1) reported a modest but significant reduction in tobacco use. However, changes could not be definitively attributed to the intervention. In addition, the evaluation described low fidelity of delivery of all intervention components.[30] Many study participants in both tobacco control studies (B1 and B2) were at pre-contemplation stage, suggesting that interventions should have been directed at people who had not yet considered quitting.[37] Study B2 reported enhanced efforts to create tobacco-free spaces and policies to support cessation.[38,39] The same study observed that local health workers needed more support and strongly encouraged clinicians to participate in brief intervention at every available opportunity.[40,41] Both the tobacco intervention evaluations (B1 and B2) reported qualitative effects such as raised awareness of harmful patterns of use and resentment of the financial burden of tobacco plus enhanced desire to quit. No sustainable, whole-of-community or practice changes were observed for any component in either intervention. The program targeting heavy cannabis use (B3) reported a decline in cannabis use in all three communities that was greater than hypothesised (Clough et al, in press) with no published process evaluation data available at time of writing.

Intervention study B4 reported modest but significant changes in risky drinking behaviours and raised awareness of binge drinking harms in youth 18-24 years of age. The pre-post study design in one location could not definitively attribute this change to the intervention.[36] The qualitative evaluation observed constructive processes in the development of partnerships and community participation with a local perception that the participatory nature of the project conferred ownership, motivated youth participants and was thereby empowering.[35]

Program theory, underlying assumptions: Though three similar but distinct theories are proposed in Table 2a, a general program theory for these intervention studies could be framed as: Discrete intervention components targeting locally defined substance misuse issues will activate latent capacities to create an environment that favours cessation.

The resources offered by the community-focused programs aimed to provoke and support non-specific local responses such as raised awareness and self-awareness, provide opportunities for open discussion of the issue via the presence of nominally neutral outsiders and creating cessation-enabling environments (summarised and highlighted in Table 2b). Diversionary strategies as individual components or as a key strategy of B4 potentially offered resources such as relief from boredom and a sense of belonging. The intended resources related to raised awareness and desire to quit, but also auto-reflexive processes at the individual and group level, new perspective, empowerment or self-regulation and participation in action research cycles. Though all partnered with and consulted local residents and stakeholders, study B4 differed in that it was integrated with actions occurring in an already mobilised community context, whereas studies B1-3 aimed to stimulate action using local understandings of the issue. Three candidate program theories were considered relevant for 'group b'. These are specified in Table 2b.

A core tenet of the pragmatic approach of B1-3 seems to be that equitable and effective local solutions will be derived from interventions designed and implemented in partnership with community members. There is no explicit theory underpinning these research programs, nevertheless, community engagement was viewed as both ethically and pragmatically essential within action research cycles incorporating progressive feedback on program outcomes as the research was being conducted.

The program theories of intervention studies B2 and B3 explicitly included a component of presenting local prevalence information back to the community as a key to supporting or stimulating local agency and therefore action. The action research approach working in partnership to provide feedback[38,42] was designed to have this effect[41]. Researcher-provided evaluation evidence and advocacy were also activities intended to enable and mobilise local action or create a more favourable policy environment for tobacco cessation.[40] Somewhat similar to 'group a' studies, 'group b' programs began from the assumption that social support stimulated by the intervention would encourage individual level change.[30,41] It was also assumed that local stakeholders would seize on intervention opportunities in response to the study evidence. In reality, it proved difficult to initiate or sustain focused action. Participant and stakeholder intended responses were unspecified; the substance use intervention was often not prioritised by the agencies responsible for a given component; and local capacity to engage in project strategies was possibly lacking.

CBPR that is initiated by community members, as in study B4, proposed local strategies and incorporated external and local partners. Locally determined diversionary strategies that confer ownership by and involvement of youth aimed to reduce their binge drinking. These could potentially offer resources that programs translated from elsewhere cannot; e.g., local concepts of harm or responsibility; genuine control of the processes; sense of ownership; and choice and control over intervention components. Observed and described at evaluation, the effects of these processes could not be captured in a prospective, controlled study design. The authors suggest that positive outcomes reported could have been related to increasing the personal locus of control of participants and that empowering participants could directly improve the determinants of health, citing Wallerstein.[43] A candidate program theory might be expressed in these terms:

Community-owned and initiated diversionary strategies can reduce youth binge drinking by providing social resources that are more highly valued than the effects of alcohol.

Offering social or physical opportunities that are more highly valued than drinking is similar to specific individual components intended in programs of the other intervention studies in 'group b'. Studies B1-3 were not CBPR but involved action research in externally formulated intervention designs. Two related resources potentially offered by CBPR are 'empowerment' and 'enhanced locus of control'. All 'group b' projects made assumptions about participant capacity; authentic buy-in of partners or a factor that Jagosh et al. have referred to as 'partnership synergy' in realist terms.[44]

Discussion

Eight NHMRC-funded project grants supported seven intervention studies for rural and remote Indigenous populations since 2003 targeting: tobacco use (n=5); cannabis use (n=1); and binge-drinking (n=1). Three clinic-based tobacco intervention studies used RCT designs. Four community-oriented intervention studies used a cluster RCT, two MBL designs and one an uncontrolled before-and-after study. At the time of writing, their cumulative output was 33 peer-reviewed articles.

All of the interventions included components that would support individual change as well as ameliorate the social or environmental factors that could influence individual decisions about substance use behaviours. Partnership approaches were explicitly used in four of seven intervention designs. All included components delivered by or received by local Indigenous health workers or residents in the intervention communities. All of the intervention designs shared underlying principles consistent with recommendations in the NHMRC 'Roadmap' including measures to promote self-determination (e.g. consultation, involving communities in the research by feeding back data, employing local health workers).

Outcomes of the interventions

Unfortunately, none of the studies were able to demonstrate a large or socially significant reduction in levels of use of the targeted substance, nor a clear effect attributable to the intervention. Low fidelity of implementation,[30] weak study designs[36] and inevitably small sample sizes[24] undermined the utility of the results of most studies.

Study designs and program theories

A gradient of engagement with theoretical processes of change is apparent in the collated studies.

Group (a) clinic-based controlled trials implemented 'evidence-based' approaches theorising that intervention groups receiving higher doses of clinical and social support would change smoking behaviours. The program theory assumes that the intervention will create resources for the target population; primarily on the grounds that the approach worked elsewhere. Apart from offering some training, how or why local people who were engaged to deliver the intervention would respond was not systematically examined. The study design aimed to create all or nothing conditions, like an on / off switch, either the intervention is present or it is not. Why participants did not respond as intended was not a focus of process evaluation.

Group (b) community-focused multi-level interventions appeared to incorporate implicit theories about how participants respond to project resources designed to stimulate local agency. This was usually via data feed-back and raised awareness that would empower participants to make better decisions about their health. Once again, there was no comprehensive discussion or assessment of the reasoning behind participants and stakeholder responses.

Significance of the findings

The logic of a 'black box'[46] program design is especially apparent in controlled trials which tend to assume a linear chain of causation, whereas in reality substance misuse interventions, like most behavioural intervention programs, are complex and not unidirectional.[19] Interventions have attempted to account for specific structural,[45,47] cultural[48] and geographical contexts that may influence program design; however, embedding elements of interventions sustainably while rigorously measuring effect are ongoing methodological challenges.[7,46] Complex systems under study cannot be easily or ethically controlled and participatory programs face challenges gathering empirical evidence of their effects.[6,46] Theoretical approaches offer opportunities to fill these knowledge gaps by collecting evidence about the processes of change that conventional study designs have not furnished.

Limitations

Although we have attempted to speculate broadly on the assumptions about resource-response pairs from the reported aims and outcomes, this is not the same as objectively uncovering the true theoretical mechanisms of these interventions. The program designers and partners would have more knowledge of the context, including: local relationships, local history, or timing of the intervention with respect to other significant events. Our review covers only one aspect of the major health concerns facing Indigenous populations living in remote communities, and only projects funded by one major funding body. Interventions targeting global wellbeing, health promotion or health systems that may indirectly affect substance use in remote Indigenous communities were beyond the scope of our review.

Conclusion

There have been significant efforts by NHMRC-funded researchers since 2003 to conduct intervention research to reduce substance misuse in remote Australian Indigenous communities, but the impact of this research has been very modest. The intervention studies included in this review were of high quality; well-funded and resourced; combining the efforts of excellent academics with the cooperation of community leaders and health practitioners. Despite this, the impacts of the significant investment described by these research outputs have been modest, translation to policy has been very limited and few sustainable effects have been documented. New and more comprehensive theories are needed in this difficult and complex area of behaviour change where even small changes could be important, if the mechanisms by which they occurred can be captured using an appropriate synthesis of all available evidence.

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