Cluster randomised trial of the effectiveness of Motivational Interviewing for universal prevention

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ABSTRACT

Background: The prevention of initiation of tobacco, alcohol and drug use is a major societal challenge, for which the existing research literature is generally disappointing. This study aimed to test the effectiveness of adaptation of Motivational Interviewing (MI) for universal prevention purposes, i.e. to prevent initiation of new substance use among non-users, and to reduce risks among existing users.

Methods: Cluster randomised trial with 416 students aged 16-19 years old recruited in 12 London Further Education colleges without regard to substance use status. Individualised MI was compared with standard practice classroom-delivered Drug Awareness intervention, both delivered over the course of one lesson. Prevalence, initiation and cessation rates for the 3 target behaviours of cigarette smoking, alcohol consumption and cannabis use, along with reductions in use and harm indicators after both 3 and 12 months were assessed.

Results: This adaptation of MI was not demonstrated to be effective in either intention-to-treat or sub-group analyses for any outcome. Unexpected lower levels of cannabis initiation and prevalence were found in the Drug Awareness control condition.

Conclusions: This particular adaptation of MI is ineffective as a universal drug prevention intervention and does not merit further study.

Keywords*:* Motivational Interviewing, prevention, smoking initiation, alcohol, cannabis

1. INTRODUCTION

The use of mood altering substances constitutes a risk factor for a range of possible direct harms to individual health and well-being, and particularly among children and young people, there is also the risk of escalation from lower to higher levels of risk (Institute of Medicine, 1996). Given the intractable nature of drug dependence, the associated public health burden and wider societal costs, effective methods of prevention of tobacco, alcohol and other drug use, particularly amongst the young, are likely also to be highly cost-effective (Caulkins et al. 2004).

The evidence-base on the effectiveness of interventions undertaken to prevent tobacco, alcohol and other drug use is disappointing. The vast majority of interventions with children and young people are delivered in schools. Two Cochrane systematic reviews covered the prevention of both tobacco and illicit drug use in schools, and included 94 (Thomas & Perera, 2006) and 29 trials (Faggiano et al. 2005) respectively, whilst a review of interventions for drug prevention in all settings other than schools included 17 trials (Gates et al. 2006). Seventy-five per cent (42 of 56) of studies included in the Cochrane review of the prevention of alcohol misuse were undertaken in schools (Foxcroft et al. 2002). Across these reviews, some interventions appear to exert short-term effects, whilst others appear to be ineffective. There is little high quality evidence that any interventions in schools can have any long-term effects, and the weakness of this evidence-base and the need for more research are common conclusions in these reviews.

In contrast, there is good evidence for Motivational Interviewing (MI; Miller & Rollnick, 2002), particularly so in relation to alcohol problems (Hettema et al., 2005). Adaptations of MI have promising potential for risk reduction among young people across a range of

different behaviours (see Johnston et al. 2002 for example). Baer and colleagues (2001) identified effects to endure for at least 4 years in a trial among university students, and specified the acceleration of maturational trends as a likely mechanism of effect. As far as we are aware, the existing evidence-base for MI in relation to substance misuse is entirely comprised of interventions with those who have already initiated the use of particular substances, with the exception of a small pilot trial (which included 4 non-drinkers in a sample of 34) evaluating a group intervention informed by MI (Bailey et al. 2004). It is unknown whether MI may be useful for universal prevention purposes and thus may be adapted to effectively prevent initiation of substance use.

2. METHOD

This study was undertaken as an exploratory trial in order to prepare for a later larger definitive trial designed to influence resource allocation decisions (Medical Research Council, 2000). A cluster randomised trial design was chosen to compare the possible effectiveness of MI against standard practice in the educational setting. Clusters comprised whole class groups of students. This comparison involved investigation of the potential impact of intervention in groups with heterogeneous risk characteristics, yet who provide a common targeting opportunity. The overarching hypothesis tested was that MI would reduce drug use and related risk in comparison to the standard practice group intervention, after both three and twelve months, with target drug use for the interventions being cigarette smoking, alcohol consumption and cannabis use. Both primary prevention effects (i.e. relating to initiation of use of drugs) and secondary prevention effects (i.e. among those who were already using particular substances) were sought. Ethical approval was given by the Institute of Psychiatry, King's College London.

2.1. Setting & Participants

Further Education (F.E.) Colleges in Britain are non-traditional educational and training institutions catering to large numbers of older teenage students. There is usually one F.E. college in each London borough (the local government administrative unit). As in a previous study (McCambridge & Strang, 2004), we approached all colleges within a defined geographical limit and negotiated study participation. The response was encouraging with 12 out of 21 colleges approached agreeing to participate. Age 16-19 years old was adopted as the sole inclusion criterion, and there were no formal exclusion criteria. No attention was thus paid to the prior drug use status of participants in their recruitment to the study. Student groups were specifically targeted that comprised wholly or mainly those who had not completed Level 2 education (defined as having at least 5 General Certificate in Secondary Education [GCSE] grades A – C or equivalent) i.e. those who had not achieved the conventional measure of educational attainment on completion of compulsory schooling in Britain.

2.2.Interventions

Motivational Interviewing (MI) is a highly individualised intervention (Miller & Rollnick, 2002). Its aim is to help the participant explore their own behaviour. Particular emphasis is given to perceptions of risk and problem recognition, concerns and consideration of change, and also to the activity of the practitioner in directing attention towards the resolution of ambivalence. We previously developed an intervention model for which impressive evidence of short-term secondary prevention benefit had been obtained among older teenage cannabis smokers, including impact on drinking and cigarette smoking (McCambridge & Strang, 2004; 2005). We adapted our previous intervention model (McCambridge & Strang, 2003) for this study by designing new topic material specifically for primary prevention purposes. For

example, participants were encouraged to think through and discuss a series of hypothetical situations in which they might find it difficult to refuse offers of drugs they had not previously used. We also explored the reasons for not using specific substances, and how initiation of use might affect future plans. The basic topic structure from the previous version was thus retained (McCambridge & Strang, 2003).

Drug education is not mandatory in F.E. colleges and there is considerable diversity in activity levels with little evaluation (Slym et al., 2007). As a consequence, we standardised a "Drug Awareness" (DA) control intervention on the basis of usual practice as described by college-based practitioners. This comprised a 16-question quiz on the effects of cigarette smoking, alcohol consumption and cannabis use, followed by further discussion components and the provision of leaflets giving accurate information on the effects of target drugs. The harm reduction orientation of this intervention reflected the standard approach in Britain. Absent from this DA control intervention were the opportunity to discuss personalised risks or concerns, and also practitioner behaviour designed to heighten awareness of individualised risk, elements considered to be fundamental to MI.

Both interventions were scheduled for delivery during a one-hour lesson. We agreed with the colleges that students who were older than our target age range would not be withdrawn from classes, resulting in delivery of DA to non-study participants. In addition to 2 researchers, 6 college-based practitioners were invited for workshop-based training in the delivery of both interventions and subsequently participated in the study. The majority of the interventions in both study conditions were actually delivered by the 2 researchers (n=144 and n=109 respectively). We aimed to audio-record a random sample of 1/4 MI sessions for fidelity monitoring purposes within the context of ongoing supervision, though there were difficulties

in persuading college practitioners to adhere to this target, resulting in a total of 31 MI sessions of 159 actually delivered being audio-recorded. This shortfall of 9 sessions was mostly due to some college practitioners being either uncomfortable asking participants for this to be done or about having their own practice sessions audio-recorded. There were 4 instances of problems with the equipment or its use among college practitioners, for whom participation in supervision sessions with the two researchers was less than had been hoped. The two researchers were in turn supervised by the first author.

2.3.Outcomes and Data Collection

The extent of initiation among non-users of particular substances provided a simple measure of primary prevention outcome. In line with the previously conducted study, reduced consumption was used as a proxy measure of beneficial change among those already using a particular substance (McCambridge & Strang, 2004). In addition to measures of use assessed over the past month we included measures of risk and harm for each substance as follows; nicotine dependence was measured with the Fagerstrom scale (Heatherton et al. 1991); cannabis dependence with the Severity of Dependence Scale (SDS; Gossop et al. 1995); and hazardous drinking with the Alcohol Use Disorder Identification Test (AUDIT; Babor et al. 2001); and a measure of interactional problems for each substance which counts the number of relationship problems that the young person themselves attributes to their own use (McCambridge & Strang, 2004). The AUDIT was the sole exception to the one month timeframe, where we reduced the reference period from the usual past year to be past three months in line with the needs of follow-up study. Assessments instruments were designed to be brief in accordance with the preferences of the colleges.

Study participants self-completed questionnaires at baseline and at both follow-up intervals after 3 and 12 months, either in classrooms (for the bulk of the first follow-up assessments) or in individually scheduled appointments (for all of the second follow-up assessments) as necessary. Contacts were initially made by telephone to schedule individual appointments. The researcher involved in the administration of the follow-up data collection at any college had not been involved in the delivery of interventions in that college, though was not always blind to study allocation.

2.4. Sample Size

The novelty of this study posed difficulties for sample size estimation. We based our power calculations on our previous secondary prevention work. One hundred and forty subjects per group were required to detect a consumption effect size of 0.40 after three months. This estimate was similar to the lowest effect size previously obtained for secondary prevention after 3 months (0.34 [0.1-0.6] for cigarette smoking), though is modest in comparison with the largest effect size previously obtained (0.75 [0.45-1.0] for cannabis use in McCambridge & Strang, 2004). This assumed a within-cluster variance of 0.9 and an intra-class correlation coefficient of 0.01(from the previous trial) and guaranteed 80% power at the 5% significance level. We also assumed that two thirds of all study participants would be users of each of the three target drugs requiring a total study population of 420. These assumptions used in the power calculation proved to be inaccurate (see Results).

2.5. Randomisation

Computerised randomisation was undertaken by the local Clinical Trials Unit and decisions were communicated by telephone to researchers after recruitment and baseline data collection on an individual college basis to preserve allocation concealment. We stratified allocation by

college, so that equivalent numbers of groups recruited from any one college would be allocated to each study condition.

2.6. Statistical methods

Two sets of analyses were undertaken. Firstly, an 'intention-to-treat' analysis considered the entire study population as it has been randomised, with last observations carried forward to deal with missing data. Secondly, there was an *a priori* decision to consider outcomes in sub-groups formed by drug use status at study entry, so that, for example, cigarette smoking outcomes were evaluated among those who were or were not cigarette smokers at baseline. No statistical corrections for multiple testing have been used, instead individual outcomes were interpreted in the context of their coherence with the outcome dataset in general.

It was deemed preferable to adopt a straightforward and consistent approach to analysis in light of the number of outcomes being evaluated. The binary outcomes of prevalence, cessation and initiation were modelled with logistic regression and all other outcomes presented in the tables were continuous and modelled in multiple regressions. As many of the continuous data violated assumptions of normality, change scores were created as outcome variables which reduced this problem in the multiple regression models. For both logistic and multiple regressions, the outcome model incorporated a practitioner grouping variable, dummy coded to have the 3 practitioner groups (each researcher plus all college practitioners combined) and a fourth category consisting of non-attenders. Logistic regression models also included the baseline measure of the outcome variable. Analyses were undertaken using STATA Version 9 software. The Huber/White Sandwich estimator of variance was used to control for the effects of cluster allocation in the whole class groups which had been randomised (with the STATA command "cluster").

Insert Table 1 about here

3. RESULTS

Randomisation successfully created baseline equivalence between groups – see Table 1. Other drug use was rare; only 5% (20/416) reported ever having used any other drug, with ecstasy being the most common other drug, previously used by 4% (17/416), followed by cocaine and amyl nitrate (2%, 8/416 for both). After 3 months, the MI group were followed up slightly earlier than the Drug Awareness (DA) group (96.9 days [SD 17.3] compared to 102.6 days [18.6], t= 3.15, p=0.0017). This mean difference had reduced to 2.3 days at 12 month follow-up, which was no longer statistically significant (t=0.78, p=0.436). There were no refusals to participate and follow-up rates were satisfactory (89% after 3 months [371/416] and 84% [348/416] after 12 months). The flowchart of participants through the trial is presented in Figure 1.

Insert Figure 1 about here

Attrition was not differential between the study groups (3 months 12% [25/206] MI, 10% [20/210] DA, χ^2 [1]=0.74, p=0.391; 12 months 18% [37/206] MI, 15% [31/210] DA, χ^2 [1]=0.78, p=0.378) but was not random in a number of other important respects. Older study participants were more likely to be lost to follow-up at both intervals (3 and 12 months followed-up 17.5 years mean age compared to 17.9 years lost to follow-up at 3 months, t=2.79, p=0.006, and 17.8 years lost to follow-up at 12 months, t=2.48, p=0.014); as were males at both intervals (3 months 14% [32/223] male, 7% [13/193] female, χ^2 [1]=6.22, p=0.013; 12 months 20% [44/223] male, 12% [24/193] female, χ^2 [1]=4.03, p=0.045); those

categorized as mixed race or other at 3 months (24% [9/38] compared to White, Black and Asian groups, χ^2 [3]=8.26, p=0.041); those who had ever sold drugs to friends at both intervals (3 months 29% [6/21] sold drugs, 10% [39/392] not sold drugs, χ^2 [1]=7.12, p=0.008; 12 months 33% [7/21] sold drugs, 16% [61/392] not sold drugs, χ^2 [1]=4.58, p=0.032); cigarette smokers at 3 months (19% [22/117] smokers, 8% [23/299] non-smokers, χ^2 [1]=10.76, p=0.001); and cannabis smokers at both intervals (3 months 21% [19/90] smokers, 8% [29/326] non-smokers, χ^2 [1]=12.61, p<0.001; 12 months 24% [22/90] smokers, 14% [46/326] non-smokers, χ^2 [1]=5.51, p=0.019).

3.6.Main Outcomes

There were no statistically significant between-group differences in intention-to-treat analyses for either cigarette smoking or alcohol consumption outcomes. There were also no statistically significant between-group differences when the analyses were restricted to those who were already users of these substances upon entry to the study. Outcome data for cigarette smoking are presented in Table 2 and for alcohol consumption in Table 3.

Insert Table 2 about here

Insert Table 3 about here

Cannabis use prevalence was lower in the control group at both 3 and 12 months – see Table 4. There was also less initiation of cannabis use in the control group over the 12 month study period as a whole, though the numbers involved are small (MI 14 initiators, DA 4 initiators). There were no other statistically significant between-group differences in intention-to-treat analyses nor when the analyses were restricted to those who were or were not already using

cannabis upon entry to the study, though there is a general trend towards better outcomes in the control group (see Table 4).

Insert Table 4 about here

3.7.Further Analyses

Non-attendance at interventions made little difference to observed outcomes. Non-attenders were distinct only in relation to the following outcomes; they had not reduced their frequency of cigarette smoking after 3 months (mean change score 0.48 compared to -5.6 in the reference category of the practitioner delivering most interventions; difference adjusted for intervention 6.58 [1.67-11.49], p=0.013); similarly they had not reduced the number of cigarettes smoked per day at 3 months (mean change score 0.52 compared to -1.2; adjusted difference 2.15 [0.15-4.15], p=0.037); 91% (41/45) of baseline drinkers who did not attend were still drinking after 3 months compared to 77% in the reference group (54/70; OR=3.0 [1.18-7.62], p=0.021); mean AUDIT scores had also not reduced at this same interval (change score 0.47 compared to -2.1; adjusted difference 2.57 [0.90-4.24], p=0.006). There were no differences whatsoever in outcome after 12 months between those who had attended interventions and those who had not.

There were differences in outcome apparent between the 3 practitioner groupings. These were most pronounced between the two researcher practitioners, and those which are statistically significant are presented in Table 5. Further analyses revealed no practitioner-intervention interactions in outcomes for these two. Outcomes for the college practitioner group were distinct from the reference practitioner only in the following cases; 61% (11/18) of baseline cigarette smokers were still smoking after 12 months compared to 83% (34/41)

for the reference practitioner (OR=0.36 [0.13-1.00], p=0.05); 88% (28/32) of baseline drinkers were still drinking after 3 months compared to 77% (54/70) in the reference group (OR=2.23 [1.23-4.02], p=0.008); 16% (9/57) of non-smokers at study entry initiated cigarette smoking over the 12 month study period, compared to 7% (7/103) in the reference group (OR=2.57 [1.01-6.58], p=0.049); and 21% (9/43) of non-drinkers initiated drinking during the 12 month study period, compared to 11% (8/74) in the reference group (OR=2.24 [1.21-4.18], p=0.01).

Insert Table 5 about here

A series of paired t-tests was undertaken to consider whether there was statistically significant change over time in the sub-group of baseline users of each drug regardless of study allocation. The mean number of cigarette smoking days reduced from 21.7(10.7) to 18.3 days (12.9) after 3 months (t=3.46, p=0.0008), and this mean reduction was maintained at 17.4 days (13.1) after 12 months (t=3.68, p=0.0004). The mean number of cigarettes smoked per day reduced from 6.6 (5.6) at study entry to 5.9 (5.9) after 3 months (t=1.97, p=0.0508) and to 5.6 cigarettes (5.8) after 12 months (t=2.17, p=0.0325). Mean frequency of drinking reduced from 4.4 days (6.0) to 3.7 days (5.3) in the first 3 months (t=2.34, p=0.02), though this reduction was not maintained. Mean AUDIT scores reduced in the first 3 months from 6.7 (SD 5.5) to 5.7 (5.9; t=3.45, p=0.0007) and remained reduced (5.4 [5.7] at the twelve month interval (t=3.21, p=0.0016). The mean monthly frequency of cannabis use reduced from 16.3 days (12.1) to 13.6 days (12.6) after 3 months (t=3.36, p=0.0012), and to 12.1 days (14.7) after 12 months (t=2.89, p=0.0049). Similarly the mean number of joints smoked in the previous week reduced from 10.0 (11.4) to 8.0 (10.3) after 3 months (t=3.06, p=0.0031), and to 6.2 (9.0) after 12 months (t=3.63, p=0.0005). Otherwise cigarette smoking,

alcohol consumption and cannabis use were unchanged over time among those who were using these substances at study entry.

4. DISCUSSION

No evidence supporting the use of MI for universal prevention has been obtained. This includes a lack of effect on reduced initiation of substance use, and there is also an absence of secondary prevention effects, as would be expected on the basis of prior studies, particularly on alcohol consumption (Baer et al. 2001; McCambridge & Strang, 2004; Hettema et al. 2005; Gray et al., 2005). What between-group differences there are suggest the possible effectiveness of the classroom-based Drug Awareness discussion on the prevalence of cannabis use. We view this to be very unlikely in light of the current state of the prevention literature, in which the most promising interventions are much more intensive and/or multi-modal (e.g. Faggiano et al. 2010).

Application of formal MI fidelity measures was not possible due to the novel nature of this adaptation. There are no existing validated MI fidelity measures currently available which might be used for the purposes of assessing fidelity in adaptations of MI with behaviours not engaged in by the participants. Although we could have used such measures in relation to current behaviours at study entry, existing measures also require the identification of a single target behaviour, making their use problematic in the multiple behaviour targeting context of this study. We developed and used a simpler instrument, which provided some data on the conduct of the discussion, which was unrelated to outcome (data not reported). These data do not, however, permit any valid assessment of the extent to which the intervention implemented can be accurately described as high quality MI which would not have been possible for reasons previously given. By virtue of the nature of the control intervention, we

can be confident that the structural components (i.e. the quiz questions) were delivered, though we cannot exclude the possibility that subsequent discussions were handled in ways influenced by MI. The absence of MI fidelity study is an important barrier to making inferences from this study generalisable to the possible effects of MI for such purposes more broadly.

The practitioner differences detected give rise to concern that high-quality MI was not consistently delivered, and importantly, that it was not straightforward to do so with this adaptation. Audio-recordings and supervision discussions suggested that although there was good adherence to the structure of the intervention, the sessions could not be strongly characterised as embodying the spirit of MI. Although interventions were delivered in a person-centred way, they were not consistently successful in elaborating the participants thoughts about behaviours with which they were not involved. The basic concept was that it would be possible to have the participant consider the possibility of engaging in these behaviours and then for them to describe discrepancy with important values and goals. As this was not consistently achieved, despite some promising pre-trial developmental work, this suggests an obvious limitation to the value of this approach. These individual discussions were nevertheless clearly distinct from the main content of the control condition where the focus was on the provision of information in groups.

Although baseline data were included in outcome models, there was also no random allocation of practitioners to colleges. It is interesting that there is variability across substances in these practitioner differences with Practitioner 1 achieving better outcomes for alcohol consumption and cannabis use and Practitioner 2 being more successful for cigarette smoking. It has also been known for some time that these types of practitioner effects on

achieved outcomes both exist across different types of counselling interventions and are also variable across outcomes (Luborsky et al. 1985). It will be preferable to monitor adherence more formally in future studies of MI adaptations, adapting existing process instruments if necessary, and also studying carefully the content of interventions delivery with multiple behavioural targets. The outcome dataset has a complex multi-level structure and perhaps we could have explored it more fully with more sophisticated models. We preferred to keep the analyses as simple as possible in light of this complexity and the null findings suggested clear limits to the value of further data analyses.

There are other study limitations to be borne in mind. We were less successful than we had hoped in recruiting and retaining college-based practitioners in the study following the offer of training, and dedicated remuneration and protected time to deliver study commitments will be appropriate for further studies in this setting. Outcome data evaluated here have been entirely self-reported. Prevalence levels at study entry are broadly in line with what might be expected, taking account of existing survey data (Goddard & Green, 2005; Fuller 2005). However, the nature of change over time among relatively small sub-samples requires examination. It would appear that the monthly rate of cannabis initiation was approximately 9 times higher during the first 3 month study period (11 cases MI, 3 cases DA), than in the subsequent 9 month period (3 cases MI, 1 case DA). Some participants may be more likely to honestly report drug use subsequently if they have received MI. It will be important to be vigilant about this possibility in future studies of MI.

Is there an effect favouring DA on cannabis prevalence here, notwithstanding the above caveats? Variable impact across substances is indeed plausible, and there was greater statistical power to detect an effect on cannabis initiation. It is unclear, however, why such an

effect might occur specifically on the use of this substance and not on others. In addition to what is known about the intensive and multi-modal nature of effective drug prevention (e.g. Faggiano et al. 2010), this possibility is not supported by the most recent review of MI effectiveness by Lundahl and colleagues (2010). They found MI effects on cannabis use to be as large if not larger than those for tobacco and alcohol in studies with strong comparison groups. If interventions such as DA really do have these effects, then their lack of prior study may be responsible for this appearing so surprising. We do not, however, view this as a promising line of enquiry. The change over time data suggest the possibility of both interventions having equivalent effects, or indeed of study participation itself exerting a positive influence, although the paucity of differences between attenders and non-attenders suggests the opposite. In any case, inferences of effects in trials should be reserved for differences between study conditions, rather than across them.

We believe it is more likely that neither intervention has been effective in changing the behaviour of the study participants, and if this is proven to be correct, there is an important implication to be considered: Combining pursuit of primary and secondary prevention effects has apparently served to blunt the impact upon existing substance use that should be expected on the basis of previous secondary prevention studies, most notably upon alcohol consumption, for which there is the largest and most positive evidence-base (Baer et al. 2001; Hettema et al. 2005; Gray et al., 2005). It seems likely that in trying to prevent young people from doing something which they are not, we have unfortunately hampered the possibility of healthy influence of their current behaviour.

Consideration of the nature of the study population and setting is important to evaluation of the generalisability of these findings. Further Education colleges attract diverse students. We

specifically targeted for inclusion those who had not achieved the basic standard in compulsory schooling to age 16. Our study population is thus best characterised as comprising those who have failed in, or been failed by, the school system and who nevertheless make further attempts to acquire education and skills training. This population may not be as receptive to intervention as other groups of young people for a multitude of reasons to do with heightened risk and vulnerability. Our age group is also older than that commonly targeted for drug prevention purposes.

This is a single study of a novel adaptation of MI to a fundamentally different type of target: - prevention of initiation of a new behaviour. Inference of ineffectiveness of MI should be restricted to this particular model of adaptation of MI, and to this specific population, who are appreciably older than many other populations targeted for universal drug prevention, and for whom lack of success in conventional education may be a marker of wider resistance to intervention. It remains possible that a discussion in the spirit of MI could focus upon resilience rather than risk factors and effectively deter initiation of drug use. To explore this possibility requires further developmental work adapting MI for this purpose. It may, however, be the case that actual involvement in substance use (and perhaps also experience of heightened risk or harm) is necessary for MI to exert influence on behaviour. Future work should consider carefully the age tailoring and the detailed content of MI for both universal and more targeted applications. Rethinking prevention to encompass a lack of direct focus on individual behaviour may provide further possibilities for study (Bonell et al., 2007; Newbery et al., 2007).

Figure 1: Participant Flowchart

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