ORIGINAL ARTICLE

The MOSEXY trial: mobile phone intervention for sexual health in youth—a pragmatic randomised controlled trial to evaluate the effect of a smartphone application on sexual health in youth in Stockholm, Sweden

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ABSTRACT
An estimated 350 million cases of STIs occur globally each year. In Sweden, Chlamydia is the most common STI with approximately 30 000 cases annually, disproportionally affecting youth. National surveys report low condom use among youth. Smartphone coverage is high among this tech-savvy group. In collaboration with youth, we developed an interactive smartphone application comprising games, peer experiences and information snippets to promote condom use.

Objectives To evaluate in a randomised controlled trial, the effectiveness of this smartphone application to improve condom use among youth in Stockholm, Sweden.

Methods This two-arm, individually randomised controlled trial was implemented through the Youth Health Clinics (YHC) in Stockholm, Sweden. Youth aged 18–23 years, who owned a smartphone and had ≥2 sexual partners during the past 6 months were eligible. The intervention delivered the interactive elements described above over 180 days. The control group received a 'dummy' application. Both groups received standard of care at the YHC. The primary outcome was proportion of consistent (100%) self-reported condom use at 6 months. Secondary outcomes included self-reported number of partners, occurrence of STIs/ pregnancy and STI tests during the study period. An intention-to-treat approach was used.

Results 214 and 219 youth were randomised to the intervention and control groups, respectively. Consistent condom use was reported for 32/214 (15.0%) in the intervention group and for 35/219 (16.0%) in the control group (OR 0.9, 95% CI 0.5 to 1.6). No significant differences in secondary outcomes were seen.

Conclusion We were unable to detect an effect of the intervention. Future research should focus on targeting different subgroups within the overall risk group, with tailored mHealth interventions. The potential for such interventions in settings where sexual health services are unavailable should be evaluated.

Trial registration number ISRCTN13212899.

INTRODUCTION

Chlamydia trachomatis remains the most commonly diagnosed bacterial STI in high-income countries, disproportionately affecting the youth, despite screening, testing and effective treatment being available.[1 2] Reported levels of condom use at last intercourse among youth range from 25% o 55%, depending on setting and studied population.[3 4] Sweden has a long tradition of well implemented sexual health promotion strategies targeted to young people, including mandatory sexual health education in schools, a national network of Youth Health Clinics (YHC), free condom distribution and free testing/treatment for STIs. Nevertheless, levels of C. trachomatis infections stay high, particularly among youth,[5] indicating the need for innovative efforts to improve condom use. Sweden reports 337 cases per 100 000 population. In Europe, only UK, Norway, Denmark and Iceland report higher numbers.[6] An objective comparison of the STI burden between countries is challenging as reporting and national screening practices vary.

Using mobile devices to address health priorities (mHealth) among target populations is gaining popularity.[7] mHealth interventions are apposite for youth and for sexual health as: (A) mobile phone ownership is high (98% overall in Sweden, 92% smartphones);[8] (B) the time spent on and familiarity with smartphone technologies is high among youth; and (C) a sexual health-related intervention can be delivered discretely. Systematic reviews of sexual health interventions delivered by mobile technologies indicated increased knowledge of STIs, increased retesting after infection and increased clinic attendance.[9 10] A meta-analysis of mHealth interventions to reduce STIs showed an improvement of condom use, delay of sexual activity and higher 'safe sex' knowledge.[11] Thus far, the focus has been on exploring the effects of interventions delivered via computer, email and text messages.[9–14] An application (app) on a mobile device allows more dynamic engagement and interaction between the user and the technology than digital interventions previously tested.[15]

As recent evidence of mHealth interventions on improving condom use have indicated promise,[11] given the suitability of using an mHealth approach targeted to youth,[12] and the possibility to scale up at a low cost[7] if proven successful, we evaluated in a pragmatic randomised controlled trial the effectiveness of an interactive smartphone application to improve condom use and promote sexual health among youth in Stockholm, Sweden.

METHODS

Study population and recruitment

The study was conducted at YHCs in Stockholm County. YHCs form a nationwide network of 250 clinics across Sweden. The clinics provide contraceptive counselling and sexual health services to youth aged 12–23 years. Of the 33 clinics in Stockholm County, the trial was implemented at eight YHCs. These eight clinics, located across the county, were run by the same administering body. All youth >18 years who attended the clinics were assessed for eligibility by a member of the research team. Youth <18 years were not recruited to obviate the need for informed consent from parents. Given the sensitive nature of this trial and to assure confidentiality, we elected to include participants who could provide consent themselves. Eligible participants were provided written information on the study, and a research assistant was available to clarify any questions. Each participant provided written informed consent at the clinic.

Inclusion and exclusion criteria

Inclusion criteria included: (A) age 18–23 years; (B) smartphone owner; and (C) >2 sexual partners during the previous 6 months. Youth who did not wish to participate or women who exclusively had sex with women were excluded from the trial.

Randomisation

Eligible participants were individually randomised in a 1:1 ratio to either control or intervention arms. Stratified randomisation by sex was performed. Within each stratum, block randomisation (blocks of 4 and 6) ensured balanced representation in the two treatment arms as recruitment progressed. A remote central randomisation site generated the sequences by computer and ensured allocation concealment. Each participant was provided personal log in details, in sealed envelopes according to randomisation number. This resulted in the intervention group downloading the intervention app onto their phone. Similarly, the control group logins allowed download of a 'dummy' app containing only study questionnaires. Research staff at the site were available to assist in the download and train participants in the use of the app. The trial was therefore open label at the clinical sites; however, the analysis was conducted blind. Baseline data were collected after inclusion into the study.

Intervention

The intervention consisted of a smartphone app to promote safe sex among youth called 'Skyddslaget' ('protection team'). The app delivered youth friendly 'safe-sex and STI' relevant snippets of information to participants on their phones. In addition, it had an interactive element that included weekly games and quizzes, related to safe sex, condom usage and STIs. There were also personal stories related to sexual risk-taking narrated by peers. Activities/information snippets were changed periodically over the 6-month intervention period. Participants in the interventions arm received between two to five new activities/information snippets per day for the whole study period. The app was developed based on individual interviews and focus group discussions with youth and considering health behaviour change models, that is, the Transtheoretical Model of change and the Integrated Behavioural Model. Details of the intervention are described elsewhere.[16]

Both groups received routine standard of care at the YHCs, which included routine access to testing and treatment services, access to contraceptives and counselling services.

Follow-up

All follow-up was done remotely over the internet. Data were collected at baseline, at month 3 and at month 6. Identical follow-up questionnaires were embedded into the app for both groups. Responses sent by the participant electronically were stored on a secure database. In case of non-receipt of a response within 7 days of the expected date of receipt, three attempts at contact the participant by text message or email were made. Participants were considered lost to follow-up if there was no response during this time. The end of study was defined as day 180 postenrolment.

Outcome measures

Primary outcome: self-reported condom use during the past 6 months, that is, proportion of sexual partners (vaginal/anal intercourses) with whom a condom was always used, expressed as a percentage. Those who had a score of 100 were classified as 'fully protected', and those with a score of <100 were categorised as 'unprotected'.

Secondary outcomes: (1) self-reported number of sexual partners during the study period (mean); (2) STI testing (yes/no); (3) occurrence of pregnancy (yes/no); and (4) occurrence of STI (yes/no) during the study period.

Sample size

Sample size was estimated on the assumption that the smartphone intervention would increase the self-reported condom use among sexually active youth in Stockholm County from 50% (previous surveys) to 70%. The minimum sample size was estimated to be 124 per arm. This sample size was sufficient to detect the estimated difference in self-reported condom use between the two groups with 90% power at significant level α=0.05. Loss to follow-up was calculated at 40% based on average attrition rates in internet-based trials.[17 18] This gave a final sample size of 207 in each arm, that is, 414 in the trial.

Statistical analysis

The primary analysis approach was intention to treat with a missing at random assumption.[19] Crude and adjusted ORs with their 95% CI, comparing intervention and control groups, were calculated. Analyses were adjusted for sex, proportion of condom use at baseline, relationship status at baseline and previous experience of STIs. Logistic regression models were used for primary and secondary outcomes. The primary approach used to handle missing data was last observation carried forward. However, best-case scenario (eg, 0% unprotected intercourses) and worst-case scenario (eg, 100% unprotected intercourses) were also calculated for each outcome. A secondary complete case analysis excluding patients with missing data was also done. Subgroup analysis for sex was predefined. STATA V.16 was used for all analyses. A p value of <0.05 denoted statistical significance. All tests were two sided.

RESULTS

Participants were recruited from October 2017 to April 2018. In total, 972 youth were screened for eligibility, and 539/972
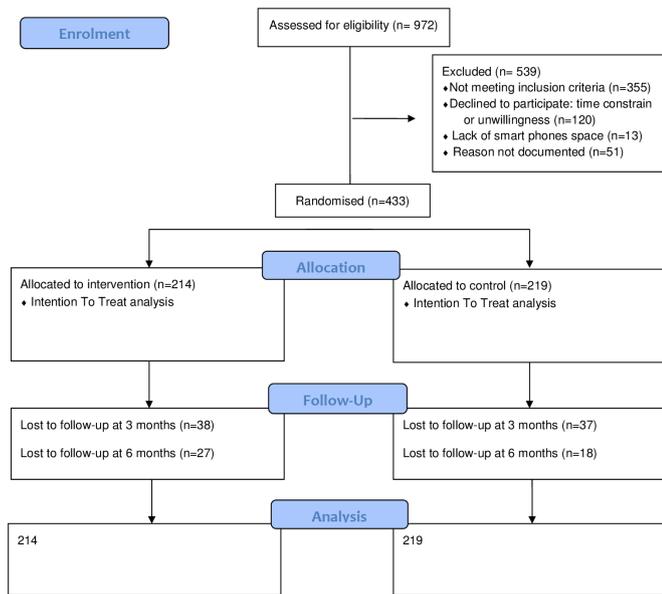
Figure 1 CONSORT flow diagram MOSEXY trial. CONSORT, Consolidated Standards of Reporting Trials; MOSEXY, MObile phone intervention for SEXual health in Youth.

(55.5%) were excluded. Among those excluded, 355/539 (65.9%) did not meet the inclusion criteria, most commonly for not having had ≥2 partners during the last 6 months (339/355, 95.5%). Other reasons for exclusion included lack of interest (100/539, 18.6 %), or time limitation (20/539, 3.7%) (figure 1). A total of 433 youth were randomised (214 and 219 to the intervention and control arms, respectively). In total, 305 participants answered all three questionnaires. Overall, loss to follow-up was 29.6% (128/433). Disproportionally more men (60/141, 42.5%) than women (68/292, 23.3%) were lost to follow-up. Baseline characteristics between those who completed the study and those lost to follow-up were similar. The baseline characteristics of the participants are presented in table 1.

Primary outcome

In the intervention group, the proportion of participants 'fully protected' as per self-reported condom use was 15.0% (32/214) at endpoint. For the control group, this was 16.0% (35/219). There was no significant difference detectable between the two arms in the unadjusted (OR 0.9 CI 0.5 to 1.6) or adjusted analyses (OR 1.0 CI 0.6 to 1.8) (table 2). The result remained consistent in best and worst case analyses and complete case analyses (table 3).

Table 1 Participant characteristics and sexual health information at baseline by intervention and control group

	Intervention (n=214)	Control (n=219)	All (n=433)
Sociodemographic characteristics			
Age mean (range)	20.2 (18–23)	19.9 (18–23)	20.0 (18–23)
Female sex, n/N (%)	144/214 (67.3)	148/219 (67.6)	292/433 (67.4)
Education, n/N (%)			
Elementary school	8/214 (3.7)	14/219 (6.4)	22/433 (5.1)
Upper secondary school	162/214 (75.7)	170/219 (77.6)	332/433 (76.7)
University	44/214 (20.6)	35/219 (16.0)	79/433 (18.2)
Occupation, n/N (%)			
Working/student	208/214 (97.2)	209/219 (95.4)	417/433 (96.3)
Unemployed	6/214 (2.8)	10/219 (4.6)	16/433 (3.7)
Living arrangements, n/N (%)			
Living with parents	159/214 (74.3)	165/219 (75.3)	324/433 (74.8)
Left parents' home	55/214 (25.7)	54/219 (24.7)	109/433 (25.2)
Relationship status, n/N (%)			
Presently single	93/214 (43.5)	95/219 (43.4)	188/433 (43.4)
One or more sexual partners (not in a steady relationship*)	103/214 (48.1)	95/219 (43.4)	198/433 (45.7)
Sexual health characteristics			
Heterosexual, n/N (%)	206/214 (96.3)	206/219 (94.1)	412/433 (95.2)
Mean age at first intercourse	15.8 (12–20)	15.8 (11–21)	15.8 (11–21)
Mean number of lifetime partners	17.1 (2–110)	14.3 (2–90)	15.8 (2–110)
Ever experienced pregnancy, n/N (%)	26/214 (12.2)	30/219 (13.7)	56/433 (12.9)
Contraceptive use (women only), n/N (%)	102/144 (70.8)	109/148 (73.6)	211/292 (72.3)
Characteristics reflecting sexual risk			
Fully protected intercourses past 6 months (100% condom use), n/N (%)	19/214 (8.9)	25/219 (11.4)	44/433 (10.2)
Concurrent sexual relationships (yes/yes I think so), n/N (%)	154/214 (72.0)	149/219 (68.0)	303/433 (70.0)
Alcohol/drug with temporary partner (always/often), n/N (%)	118/214 (55.1)	105/219 (48.8)	223/433 (51.5)
Ever had STI, n/N (%)	88/214 (41.1)	89/219 (40.6)	177/433 (40.9)
Testing habits for STI, n/N (%)			
I never tested	17/214 (7.9)	23/219 (10.5)	40/433 (9.2)
I test once per year	75/214 (35.1)	77/219 (35.2)	152/433 (35.1)
I test more often than once per year	122/214 (57.0)	119/219 (54.3)	241/433 (55.7)

*A steady relationship was ascribed to a participant with only one partner, with both members of partnership being mutually 'faithful' to each other sexually.

Table 2 Primary and secondary outcomes

	Participants		Adjusted analysis*	
	Intervention (n=214)	Control (n=219)	OR (95% CI)	P value
Primary outcome (ITT n=433)				
Fully protected intercourses, n/N (%)	32/214 (15.0)	35/219 (16.0)	1.0 (0.6 to 1.8)	0.97
Secondary outcomes (ITT n=433)				
Mean number of partners	4.4	4.4	0.9 (0.6 to 1.2)	0.43
Occurrence of STI,† n/N (%)	69/214 (32.2)	69/219 (31.5)	1.1 (0.7 to 1.6)	0.83
STI testing,† n/N (%)	180/214 (84.1)	168/219 (76.7)	1.5 (0.9 to 2.5)	0.08
Occurrence of pregnancy,† n/N (%)	35/214 (16.4)	39/219 (17.8)	0.9 (0.6 to 1.6)	0.80

*Adjusted for sex, condom proportion at baseline, relationship status at baseline and previous experience of STI.
†Worst case scenario imputed for missing values, that is, yes tested positive for STI, yes experienced pregnancy and yes tested for STI during study period.
ITT, intention to treat.

Secondary outcomes

No significant differences were detectable on any the four secondary outcomes between the two groups for unadjusted or adjusted analysis (table 2).

Subgroup analysis

No differences in effect on the primary outcome by subgroup (sex) were detectable.

DISCUSSION

To our knowledge, this is the first randomised trial of a mHealth intervention for safe sex in Sweden. It is also the first trial using an app, developed to promote condom use and sexual health, as compared with emails and text messages.[10 11 14] We were unable to detect an effect of the intervention on the primary or any of the secondary outcomes.

Strengths and weaknesses of the present trial

Strengths in the present study are the pragmatic study design in a real-world setting. The broad inclusion criteria allowed a wide cross-section of youth representing the target population to participate in the study, in a setting where sexual risk-taking is common. The intervention was suitable to the lifestyle of the youth, as they are intensive users of digital technology on mobile phones. In addition, it allowed discrete use and could thus lower utilisation barriers compared with traditional counselling on sexual health related issues. This advantage of discrete use of a sexual health app could be undermined by challenges to privacy given that youth frequently interact with each other's phones.[20]

The intervention, over 6 months, focused on different aspects of condom use. It considered behaviour change methods/models and aimed to normalise condom use, provide practical information and build the necessary trust and confidence to negotiate

Table 3 Primary and secondary outcomes: complete case, best/worst case analyses.

	Participants		Adjusted analysis*	
	Intervention	Control	OR (95% CI)	P value
Primary outcome				
Fully protected intercourses, n/N (%)				
Complete case†	25/145 (17.2)	23/160 (14.4)	1.4 (0.7 to 2.8)	0.30
Best case‡	94/214 (43.9)	82/219 (37.4)	1.4 (0.9 to 2.1)	0.10
Worst case§	19/214 (8.9)	19/219 (9.7)	1.2 (0.6 to 2.4)	0.66
Secondary outcomes				
Mean number of partners				
Complete case†	4.1	4.3	0.8 (0.5 to 1.2)	0.32
Best case‡	2.8	3.1	0.8 (0.5 to 1.1)	0.11
Worst case§	6.0	5.8	1.1 (0.8 to 1.5)	0.73
Occurrence of STI, n/N (%)				
Complete case†	30/145 (20.7)	28/160 (17.5)	1.2 (0.7 to 2.5)	0.48
Best case‡	35/214 (16.4)	36/219 (16.4)	1.0 (0.6 to 1.6)	0.91
Worst case§	69/214 (32.2)	69/219 (31.5)	1.1 (0.7 to 1.6)	0.83
STI testing, n/N (%)				
Complete case†	111/145 (76.6)	109/160 (68.1)	1.4 (0.9 to 2.4)	0.17
Best case‡	111/214 (51.9)	109/219 (49.8)	1.1 (0.7 to 1.6)	0.78
Worst case§	180/214 (84.1)	168/219 (76.7)	1.5 (0.9 to 2.5)	0.08
Occurrence of pregnancy, n/N (%)				
Complete case†	1/145 (0.7)	5/160 (3.1)	0.2 (0.0 to 1.9)	0.17
Best case‡	1/214 (0.5)	6/219 (2.7)	0.2 (0.0 to 1.4)	0.09
Worst case§	35/214 (16.4)	39/219 (17.8)	0.9 (0.6 to 1.6)	0.80

*Adjusted for sex, condom proportion at baseline, relationship status at baseline and previous experience of STI.
†Complete case, that is, participants that answered all follow-up questionnaires.
‡Best case scenario imputed for missing values, that is, 0 partners, no tested positive for STI, no did not experience pregnancy and no did not test for STI.
§Worst case scenario imputed for missing values, that is, 10 or more partners, yes tested positive for STI, yes experienced pregnancy and yes tested for STI during study period.

condom use. Therefore, we anticipated a positive effect on risk-taking behaviour. Interactive healthcare apps appear to have largely positive effects on users, in that users tend to become more knowledgeable, feel better socially supported and may have improved behavioural outcomes compared with non-users.[21] More specifically with regard to sexual health promotion, interactive IT-based interventions are effective for learning about sexual health and show positive effects on self-efficacy intention and sexual behaviour.[22]

Fidelity of the intervention: participants received the app exactly as per allocation. This was assured as login details were linked to randomisation number, and the app was downloaded in the clinic in the presence of the study midwife. Available data on engagement with the app in the intervention arm indicate that on average, a participant interacted with the app 43 times over the 6-month intervention period, that is, a little under twice a week.

Except for recruitment, all other contacts were remote, via the app. This optimised trial logistics. A potential strength of online trials is an appreciation of the anonymity, especially for a sensitive subject like sexual health.[10]

A cluster randomised trial design was not implemented as the aim was to look at the effect of the intervention at the level of the individual. Furthermore, youth tend to change clinics within the county between visits, challenging the integrity of cluster.

To minimise contamination in our trial, we did not recruit >1 participant per household, though contact between participants at school/clubs could not be ensured. Contamination between groups in the clinic was unlikely; as sexual health is personal, youth visit clinics individually.

Self-reported outcomes are susceptible to recall/social desirability bias.[23] However, an alternative for an objective primary outcome in relation to condom use behaviour was not feasible in this trial. We asked participants to recall the number of sexual partners and the number of partners with whom a condom was always used at every intercourse over the previous 3 months. After 3 months, we repeated the same questions. The end-point measure was a sum of the previous measurements. Recall bias could occur in two key subelements related to this measure, that is, poor recall in the total number of partners and poor recall of condom use at each intercourse. Another limitation was the under-representation of men in the trial that reflects the proportion of men using YHC services.

One disadvantage with an RCT implemented online is a high rate of loss to follow-up. A systematic review reported 36%–47% loss to follow-up for online RCTs.[24] Although the attrition seen in our trial was lower, it is still likely to contribute to bias. A selection bias caused by a 21% rate of non-consent (120/553) cannot be ruled out. High rates of non-consenters (17.0%) have previously been described in youth-targeted internet-based trials.[25]

Other similar studies

The last decade has seen the development of digital intervention aimed to improve sexual health.[11–13 26–28] While results have been promising, the rapid advancement of technology makes comparison between interventions difficult. There are also wide variations in populations studied and outcomes measured.[10] We found one RCT reporting evidence from a smartphone app designed to increase condom use and sexual health; however, both intervention and control arms inadvertently received the intervention.[25]

An RCT evaluating the effect of a Facebook page that provided information on sexual health for 8 weeks used the same outcome measures as in our study. Also similarly, youth could decide the level of interaction desired.[26] The intervention did not increase condom use but prevented a decrease over time compared with the control group.[26] Another RCT evaluating effect of text messages and emails sent out to the intervention group over 12 months[13] was unable to detect an effect on condom use.[13]

A study with different outcome measures from our study (condom use ranging from *never* to *always*) reported increased condom use by interaction with a website delivering tailored messages related to answers in previous questionnaires.[27] It is possible that the younger age of the participants in that study, a more individually tailored design, and a Likert scale outcome were components that contributed to a positive result.[27] Yet another single-session intervention where participants were guided by a virtual consultant through a web-based programme reported reduced self-reported rates of unprotected sex after 3 months (Likert scale outcomes).[29]

Overall, the effectiveness of mHealth interventions appears to decrease with follow-up time.[11] Studies with a follow-up time of 1–5 months had higher impact on condom use than those with followed-up time of 6 months or more. Likewise in our study, the intervention had a more positive effect on condom use at the 3-month follow-up compared with the 6-month follow-up.

Possible explanations for our study results

High attrition could partly be because participants did not request the intervention; it was presented to them. Condom non-use might not be appreciated as problematic by youth. For conditions perceived as problematic, for example, heavy drinking or a weight problem, participants would be more motivated to stay in the study. Although the high attrition rates in this trial could be related to the internet-based design, it could also indicate that participants did not find the app engaging enough. A close relationship between attrition and usage of the intervention has previously been described.[30]

Another reason for lack of effect could be the assumptions to calculate power were over optimistic with regard to effect size. Baseline condom use was lower than we had anticipated (10.2% against an assumption of 50%); therefore, the intervention could have been expected to have a larger effect, given an even lower baseline. However, this was not the case; there was no effect detectable with a similarly low rate of condom use in both arms, making the likelihood of a type 2 error extremely low.

We assumed the intervention would increase self-reported condom use from 50% to 70%. In retrospect, given the low baseline use, an assumption of even a smaller increase would have been appropriate.

There is a possibility that the intervention would benefit from targeting youth in earlier adolescence when a desired behaviour is yet to be learnt, rather than later when changing a behaviour, is more challenging. Given the higher rates of loss to follow-up among men, the intervention appeared more attractive to the female users, indicating that intervention needs to be tailored to gender. Despite non-significant results, using an app to promote sexual health might still potentially show benefit if targeted perhaps to a younger age group and designed differently to make it suitably engaging to the proposed group.

CONCLUSION

In conclusion, evidence from our internet-based randomised trial did not suggest that an interactive smartphone app could result

in significantly increased condom use among youth. However, our results notwithstanding, the use of apps to promote sexual health among youth is still an attractive one, given its suitability for tech-savvy young people and the discretion it facilitates in utilisation given the sensitivity of sexual health. Furthermore, mHealth interventions are important in settings were routine care is not available or accepted. Future research should focus on targeting different subgroups within the overall risk group, such as young teenagers and young men. The development of the interventions should be done in close collaboration with behavioural scientist and the target group. It is important that the app is developed to engage and sustain interest. The potential for such an intervention in settings where routine sexual health services for youth are unavailable has not been tested and needs to be studied in adequately powered trials.

Key messages

► mHealth interventions are suitable for the tech-savvy youth population especially for sensitive subjects such as sexual health.
► mHealth interventions aimed to increase condom use have shown promising results.
► Our trial of an interactive smartphone application did not show an effect on increasing condom use among sexually active youth.

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