ISRCTN16059206 https://doi.org/10.1186/ISRCTN16059206

Prevention, Access and Risk Taking in Young People

Submission date
31/01/2007

Recruitment status
No longer recruiting

Registration date
05/03/2007

Overall study status
Completed

Last Edited
01/10/2015

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many premature adult deaths and chronic health and wellbeing concerns result from risky behaviours that start during adolescence, such as cigarette, drug and alcohol use, unsafe sexual practices and lack of attention to road safety. The adolescent years are also the time when mental health problems such as anxiety and depression are most likely to begin. We are conducting a two-part study. The first part focuses on whether training of doctors and nurses in ways of communicating with young people about their health and wellbeing and discussing ways to reduce risk will increase detection of risk-taking and emotional issues, and increase the chances of adolescents making lifestyle changes to reduce their risk-taking behaviour. The second part studies whether helping the entire practice become more youth-friendly means that young people are more engaged and likely to return for other health concerns, and whether the best ways of communicating with young people are now part of the culture of the organisation.

Who can participate?
Young people aged from 14 to 24 visiting a doctor or nurse at one of 42 general practice clinics across the state of Victoria, Australia are able to participate. Parents of young people in this age group attending these clinics may also participate.

What does the study involve?
The first study involves the young person completing a series of surveys about themselves, their behaviour, and their consultation with the doctor or nurse. The first survey is usually completed within two days of the consultation. There are follow-up surveys with the same young person 3 months and 12 months after the consultation. The second phase of the study involves three separate surveys. The first is completed before the consultation and asks demographic questions. The second survey is usually completed after the consultation and asks the young person questions about their lifestyle and behaviour. The final survey asks the young person questions about the consultation with the doctor or nurse. This survey process is repeated at the same practice with a different group of young people after 12 months. The parent survey asks parents of adolescents and young adults about their views about health care for young people.

What are the possible benefits and risks of participating?
The surveys do contain questions of a sensitive nature, and there is the potential that the

questions may raise health concerns for participants. This will be made known to all participants beforehand, and they will be advised that they should skip over any questions that they do not feel comfortable answering. All participants are given a debriefing 'Resource List' of avenues for assistance for health concerns. They are also given the opportunity to be contacted by a researcher (clinician) if they want further assistance. Participants under the age of 18 are entitled to participate unless the doctor or nurse considers that they are not mature enough to make a decision to participate; in this scenario we seek parental consent for participation if the young person wants to be involved. Participants may benefit if high-risk behaviours are detected and appropriate counselling is provided, thus possibly avoiding the impact of such behaviours. Similarly, the intervention may prevent high-risk behaviours from developing. Individual practices will become more 'youth friendly' as a result of participation in the study, thus making better access to care possible for many young people beyond the life of the study itself.

Where is the study run from?
The study is based in the Department of General Practice at the University of Melbourne (Australia).

When is the study starting and how long is it expected to run for?
The study began in March 2007, with participants followed up for 12 months after their visit to the clinic. The second phase of the study began in 2010 and will be finished in August 2014.

Who is funding the study?
The study is funded by the Australian Health Minister's Advisory Committee (AHMAC) (Australia) and the Australian Primary Health Care Research Institute (APHCRI) (Australia). The second phase of the study is funded by the National Health and Medical Research Council (NHMRC) (Australia).

Who is the main contact?
Associate Professor Lena Sanci
l.sanci@unimelb.edu.au

Study website
http://www.party.unimelb.edu.au/

Contact information

Type(s)
Scientific

Contact name
Dr Lena Sanci

Contact details
Department of General Practice
University of Melbourne
200 Berkeley Street
Carlton, Victoria
Australia
3053
+61 (0)3 8344 6152
l.sanci@unimelb.edu.au

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Health risk screening and counselling of adolescents and youth friendly practice: a cluster randomised controlled trial in primary care

Acronym
PARTY

Study objectives
Study domain: Health risk behaviour in young people (e.g. smoking, excessive alcohol use, other drug use, mental health, unprotected sexual activity, unsafe driving) and youth friendly general practice.

Original hypotheses:
1. That a screening tool and other intervention components (training and practice visits to provide feedback) for health risk in young people will improve the clinician's detection by 25% compared to interview alone
2. That specific risk response training, including motivational interviewing, will result in at least 10% overall less uptake of risky behaviour or greater intention to change or reduction in established risk behaviour three months post-intervention compared to usual care
3. That reduction in risk taking will be sustained to 12 months
4. That the benefits for young people and society as a whole will outweigh the costs of the intervention
5. That young people's preventive care and a linkage role will be acceptable to, and feasible for, practice nurses and general practice staff

Current hypotheses as of 15/04/2014:
1. That a screening tool and other intervention components (training and practice visits to provide feedback) for health risk in young people will improve the clinician's detection by 31% compared to interview alone
2. That specific risk response training, including motivational interviewing, will result in at least 15% overall less uptake of risky behaviour or greater intention to change or reduction in established risk behaviour three months post-intervention compared to usual care
3. That reduction in risk taking will be sustained to 12 months
4. That the benefits for young people will outweigh the costs of the intervention
5. That young people's preventive care and a linkage role will be acceptable to, and feasible for, practice nurses and general practice staff

As of 14/08/2009 the anticipated start and end dates of phase I are as follows:
Anticipated start date: 15/03/2007
Anticipated end date: 31/12/2009
The initial anticipated end date for phase I was 28/02/2009. At 14/08/2009 the target number of participants for phase I was also updated; the initial target number of participants was 3000 young people from 50 general practices.

Phase II: Re-orienting general practice systems toward youth friendly care: a cluster randomised controlled trial
As of 14/08/2009 this record has been updated to include details of the phase II part of this study. All details pertaining to this phase II study can be found under the relevant section with the sub-heading 'Phase II'. Please also note that the anticipated start and end dates of phase II are as follows:
Anticipated start date: 24/08/2009
Anticipated end date: 24/08/2014

Phase II hypothesis:
Compared to the control group, a 'whole of practice' systems-level intervention, will:
1. Improve young people's willingness to return for psychosocial issues, their rating of trust and satisfaction with care by at least 0.5 of a standard deviation (SD) in outcome means
2. Result in at least 15% more parents accepting 'youth friendly' practice
3. Result in at least an effect size of 1 SD on staff self-perceived competency questionnaires
4. Improve the clinician's detection of health risk in youth by at least 10% compared to clinician training alone
5. Result in objective change in external resources, policy, structure or process to support quality care in at least 70% of practices
6. Be cost effective

Ethics approval required
Old ethics approval format

Ethics approval(s)
Phase I: University of Melbourne Human Research Ethics Committee approved on 27/02/2007 (ref: 0709280), and amendments approved on 14/08/2007, 13/05/2009, 29/06/2009 and 10/12/2012
Phase II: University of Melbourne Human Research Ethics Committee approved on 23/04/2009 (ref: 0931083), and amendments approved on 17/11/2009, 21/04/2010, 13/04/2011 and 20/03/2012

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Health risk behaviour in young people and youth friendly general practice

Interventions
Intervention and control practice staff will all receive training in engaging young people, interviewing about health risk, and making practices 'youth-friendly'.

The intervention practices will receive additional elements: use of a health risk screening tool, general practitioner and practice nurse risk-response training; and, staff support in an office-systems change for 'youth-friendly' practice.

Phase II:
Intervention practices:
1. Plan-Do-Study-Act model of continuous quality improvement for 'youth-friendly' practice systems change, including health risk screening tool; approach to confidentiality and communication skills training around health risk assessment
2. Professional mentor/critical friend to assist with practice-centered systems change
3. Feedback of young people's data into system to prioritize activities toward youth friendly care.

Control practices:
Training in young people's health but NOT youth friendly practice.

Intervention Type
Behavioural

Primary outcome measure
Comparison of intervention versus control in:
1. Clinician's accuracy in identifying risk-taking behaviour
2. Young people's uptake of risky behaviour or intention to change or reduction of established behaviour at three and 12 months post-intervention

In intervention:
Acceptability of risk screening to young people, their parents and general practice staff.

Phase II:
Comparison of intervention versus control in:
1. Young people's:
1.1. Willingness to return to general practice for psychosocial issues
1.2. Trust in the clinician, including perception of confidential care
1.3. Satisfaction with access, patient centeredness and outcomes of care
2. Parents' attitudes toward 'youth friendly' practice and perceived support in parenting adolescents
3. Staff:
3.1. Self-perceived competency in dealing with young people's issues

3.2. Communication skills with young people
3.3. Clinicians' detection of mental health issues and health risks
4. Practice:
4.1. Internal policy, structure and processes supporting quality care for young people
4.2. External resources supporting quality care (collaborators, youth participation)
4.3. Costs of general practice

Secondary outcome measures
Comparison of intervention versus control in:
1. Young people's pathways to care, trust in their clinician and likelihood of returning for future visits
2. Parents' attitudes to 'youth-friendly' practice including seeing the clinician alone and conditional confidentiality

In intervention:
1. Identification of the economic incentives/disincentives that might influence the uptake of the intervention
2. The economic efficiency of the intervention
3. Qualitative evaluation of the practice nurses' expectations, experience and effectiveness in delivering the intervention and performing a linkage function

Phase II:
Young people's health service resource utilisation

Overall study start date
15/03/2007

Completion date
24/08/2014

Eligibility

Key inclusion criteria
For practices:

Current inclusion criteria as of 17/03/2014:
1. At least one GP or practice nurse willing to participate
2. Located in metropolitan Melbourne or regional cities within an hour of Melbourne
3. Ideally have at least one practice nurse

Previous inclusion criteria:
1. See at least 25 young people (14 to 24 years old) per week
2. A core group of staff from various disciplines (including general practitioners, practice nurses, practice manager, receptionists) are willing to participate
3. Located in metropolitan Melbourne or regional cities within an hour of Melbourne
4. Ideally have at least one practice nurse

For patients:
1. Aged 14 to 24 years (inclusive)
2. Able to speak English

Phase II:
For practices:
1. Same practices with same randomisation status as Phase I

For patients:
1. Aged 14 to 24 years (inclusive)
2. Able to speak English

For parents:
1. Parent of 14 to 24 years young person
2. Attends practice (with or without young person)
3. Able to read/write English

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Phase I: 1500 young people from 40 general practices (allowing for dropout of 2 practices and 40% of young people over 12 months); Phase II: 4320 young people and 864 parents from 36 general practices

Key exclusion criteria
For patients:
1. Disability affecting capacity to provide informed consent
2. Acutely unwell (physically or mentally)
3. Severe emotional distress
4. Aged 14 to 17 years and not a mature minor and not willing for parent contact for consent

Date of first enrolment
15/03/2007

Date of final enrolment
24/08/2014

Locations

Countries of recruitment
Australia

Study participating centre

University of Melbourne
Carlton
Australia
3053

Sponsor information

Organisation
University of Melbourne (Australia)

Sponsor details
Melbourne Research Office
Level 5, Alan Gilbert Building
161 Barry Street
Carlton, Victoria
Australia
3079

Sponsor type
University/education

Website
http://www.research.unimelb.edu.au

ROR
https://ror.org/01ej9dk98

Funder(s)

Funder type
Research council

Funder Name
Australian Health Ministers' Advisory Committee (AHMAC) (Australia)

Funder Name
Australian Primary Health Care Research Institute, Australian National University

Alternative Name(s)
Australian Primary Health Care Research Institute, APHCRI

Funding Body Type

Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

Funder Name
National Health and Medical Research Council (NHMRC) (Australia)

Alternative Name(s)
NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/06/2012		Yes	No
Results article	results	30/09/2015		Yes	No