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Goal-setting, planning and self-monitoring (GPS) for gum disease

Submission date	Recruitment status	[_] Prospectively registered
01/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/08/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/04/2019	Oral Health	

Plain English summary of protocol

Background and study aims
Gum disease (periodontal disease) is a long-term condition in which the gums are inflamed (swollen). It is caused by the buildup of plaque (a sticky, colorless film of bacteria and sugars) on the teeth. Treatment of the gum disease usually involves controlling plaque levels by professional teeth cleaning and improving dental hygiene in the patient. The extent to which patients follow suggested oral hygiene advice has a major impact on the long-term success of the treatment. One of the many factors that may motivate people to follow through advice they receive from the dentist, may be the extent to which they believe they are at risk of developing gum disease. The aim of this study is to look at whether giving patients information about their risk of gum disease and helping them to monitor their oral hygiene, might affect how well they feel able to follow professional advice about their oral health.
Who can participate?
Adults who have been previously assessed by a dentist as having moderate to poor oral hygiene.

What does the study involve?
Participants are randomly allocated to one of three groups. During a routine clinical examination at the first visit, patients complete some brief questionnaires about their throughts and feelings about gum disease as well as their routine brushing and flossing behaviours. Those in group one receive standard care, which involves the dentist or hygienist takes patients through an explanation of periodontal disease and what they can do to control it using the clinic's usual guidance. Those in group two receive the same as group one with the addition of being given information about their personal risk of developing gum disease. Those in group three receive the same as group two with the addition of a brushing and flossing diary and advice on how to form a goal to improve their brushing and flossing. Participants in all groups attend a further two clinic visits, 4 and 12 weeks later, for a checkup. During the 12 week visit, patients are asked to complete the same brief questionnaires they completed at the beginning of the study.

What are the possible benefits and risks of participating?
There are no particular individual benefits in taking part in this study but participants may improve their knowledge about gum disease and could improve their oral hygiene. There are no notable risks involved with participating.

Where is the study run from?
Merivale Dental Practice (UK)

When is the study starting and how long is it expected to run for?
August 2014 to October 2016

Who is funding the study?
Oral and Dental Research Trust (UK)

Who is the main contact?
Dr Koula Asimakopoulou

Contact information

Type(s)
Scientific

Contact name
Dr Koula Asimakopoulou

Contact details
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SE1 9RW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
GPS_ODRT

Study information

Scientific Title
The effects of goal-setting, planning and self-monitoring (GPS) on behavioural and periodontal outcomes- a randomised controlled trial (RCT)

Study objectives
A psychological intervention based on individualised risk communication goal setting and planning improves psychological and clinical outcomes in patients seeking periodontal treatment, compared to treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King's College London Biomedical Sciences, Dentistry, Medicine and Natural & Mathematical Sciences, Research Ethics Subcommittee (BDM RESC), 14/09/2015, ref: HR-14/15-1739

Study design
Interventional randomised single-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Periodontal disease

Interventions
Participants are randomised to one of three groups using a random digit generator.

Treatment as usual group: Patients receive a standard routine consultation
Risk communication group: Patients receive their standard routine consultation but they are also shown information about their gum disease risk score, that has been calculated using Previser, a software package that works out risk of periodontal disease.
GPS group: Patients receive the intervention described in Arm 2 but they are also instructed to form a goal on how they will brush and floss in the near future, along with a brushing and flossing diary that they are asked to keep until their follow up visit.

Participants in all groups are followed up after 4 and 12 weeks. Follow up involves measuring plaque and bleeding scores as well and self-reported brushing, flossing and thoughts about periodontal disease.

Intervention Type
Behavioural

Primary outcome measure
Plaque and bleeding are measured using standard plaque and bleeding scores at baseline, 4 and 12 weeks post intervention.

Secondary outcome measures
1. Thoughts about periodontal disease are measured using a self-report questionnaire designed for this study at baseline and 12 weeks
2. Brushing and interdental cleaning are measured using a self-report questionnaire designed for this study at baseline, 8 and 12 weeks
3. Pocket depth is measured in mm using dental probing at baseline and 12 weeks

Overall study start date
01/08/2014

Completion date
30/10/2016

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Previously been assessed by their treating dentist as having moderate or poor oral hygiene

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25 per arm

Total final enrolment
97

Key exclusion criteria
1. Current smokers or those who have smoked within 30 days prior to the commencement of the study
2. Those who have a medical condition or who take medication likely to affect periodontal condition
3. Those with presence of diagnosed gingival overgrowth
4. Known psychiatric co-morbidity or physical disability judged to impair their ability to clean their teeth
5. Those who currently use antiseptic mouthwash or take antibiotics

Date of first enrolment
15/10/2015

Date of final enrolment
30/04/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Merivale Dental Practice
Merivale Dental Practice
94 Greenwich High Road
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SE10 8JE

Sponsor information

Organisation
Kings College London

Sponsor details
Floor 18 Guys's Tower
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SE1 9RW

Sponsor type
Other

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
Oral and Dental Research Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal.

Intention to publish date
30/10/2017

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?
Participant information sheet	version V3	25/09/2015	08/08/2016	No	Yes
Results article	results	01/09/2019		Yes	No