**INFORMATION SHEET FOR PARTICIPANTS**

***REC Reference Number: HR- 14/15-1739***

**YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**

**Title of study**

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

**Invitation Paragraph**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

**What is the purpose of the study?**

Periodontal (gum) disease is a chronic inflammatory condition caused by the build up of dental plaque on the teeth. Treatment of the gum condition is directed at controlling the plaque by professional cleaning but, this is mainly based around patient self-performed oral hygiene.The extent to which patients follow suggested oral hygiene advice has a major impact on the long-term success of periodontal 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 susceptible to such disease.

In this study we are investigating whether giving patients information about their risk of periodontal disease and helping them to monitor their oral hygiene behaviours, might affect how well they feel able to follow professional advice about their oral health.

**Why have I been invited to take part?**

We are asking all adult patients who are due to be seen by the team at Merivale Dental Clinic between October and December 2015 and who have in the past had the need to have periodontal treatment, if they would like to take part.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do decide to participate you will be given this Information Sheet to keep. You are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part will not affect the standard of care you receive and you will still be able to have the dental treatment you need. If you withdraw from the study, any data collected from you will not be retained or used in the study. You may complete the study and still request for your data to be withdrawn by contacting one of the researchers by 01.04.2016.

**What will happen to me if I take part?**

All you will need to do is attend your appointment and let your dental team professional know if you are happy to participate. The practice team will go through a medical questionnaire with you and confirm that you are suitable for the study. If so, you will be randomly allocated to one of three study groups. Random allocation means that what group you are allocated in will be determined by a computer random number generator programme, rather than by your dentist. This is standard practice for research studies of this type.

During your routine clinical examination at your first visit, the dentist / hygienist will take you through an explanation of periodontal disease and what you can do to control it using the clinic’s usual guidance. Depending on what research group you have been allocated to, this explanation may be supplemented by further advice on how to tackle the disease.

All three groups of patients will be asked to visit the clinic twice more and fill some short questionnaires. These visits will take place at 4 and 12 weeks after your regular dental appointment. As such, taking part in the study means that you would be invited to make one additional visit to what you would do normally, at 4 weeks. There will be no charge for this visit during which the dentist will look in your mouth, but they will not perform any treatment. During this second and the final visit, you will be asked to complete the same brief questionnaires you completed at the beginning of the study. There are no right or wrong answers to these questionnaires – these ask about your thoughts and feelings about periodontal disease. After completion of the questionnaires you will be assessed for your condition in the normal way for any patient attending the clinic.

On completion of the study, that is, at your third visit taking place at week 12, your teeth will be professionally cleaned regardless of what group you were allocated to.

As a means of saying ‘Thank you’ for your time in completing the study we will enter all completing participants’ names into a draw for two £100 M&S vouchers. If we find that our intervention is successful in helping patients manage their oral health better, we will make the intervention available to all patients free of charge at the end of the study.

**What are the possible risks and benefits of taking part?**

The study poses no additional risks to those involved in routine clinical care. Previous research in this area has shown us that patients enjoy taking part. If however you find any aspect of the study distressing (e.g. discussing your risk of gum disease) the research team will be available to discuss your concerns.

There are no particular individual benefits in taking part in this study but we hope that by taking part you will learn more about periodontal disease affecting your gums as well as management of this condition (helping you maintain good oral health).

**Will my taking part be kept confidential?**

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you will have your name and address removed so that you cannot be recognised from it. All questionnaires will be stored securely. The anonymised, clinical data will be made available for statistical purposes to the developers of the software the practice use routinely to calculate patients’ periodontal disease scores.

**How is the project being funded?**

The project is funded by a charity known as the Oral and Dental Research Trust and by the Dental Institute at King's College London.

**What will happen to the results of the study?**

The information attained from this study will not be used for any treatment purposes but we hope that this research will help us tailor our information and treatment to best meet each patient’s needs. If you wish to have information regarding the results of this study, these will be available to you upon request at completion.

**Who should I contact for further information?**

If you have any questions or would like to obtain further information about this study, you can contact any of the research team

At King’s College London:

**Dr Koula Asimakopoulou** or **Professor Tim Newton**

KCL, Dental Institute, Population and Patient Health, Guy’s Hospital, Guy’ Tower Floor 18, Great Maze Pond, London., SE1 9RW Telephone: +44 (0) 207 848 5145. Email: koula.asimakopoulou@kcl.ac.uk or tim.newton@kcl.ac.uk

At the Merivale Dental Practice:

**Matthew Nolan,** 94 Greenwich High Rd, London SE10 8JE
tel; +44 (0) 20 8692 9963. Email: reception@merivaledental.com

**What if I have further questions, or if something goes wrong?**

If you have any further questions about this study please feel free to contact any of the researchers whose contact details appear above who will be very happy to answer any questions you may have about the study.

If this study has harmed you in any way or if you wish to make a complaint about the conduct of the study you can contact King's College London using the details below for further advice and information: The Chair, BDM RESC, King’s College London, Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH.

Or email: rec@kcl.ac.uk