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Two patient decision aids (PDAs) in a survey of patients' feelings about different approaches to prosthodontic consultation

Submission date
26/07/2023

Recruitment status
No longer recruiting

Registration date
28/07/2023

Overall study status
Completed

Last Edited
28/11/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Dental therapies are increasingly provided with a focus on individual patient requirements and emotional well-being. Any patient-centered care of this type needs to be grounded in a meaningful relationship between the patient and the dental team, communication being the key to establishing such a relationship. It takes communicative and interpersonal skills on the dentist's part to gather all the patient-specific information that is required for a correct diagnosis and to select an appropriate process that will optimally meet each individual's therapeutic needs. Patient outcomes can be improved further by one-on-one consultations in accordance with the principle of 'shared decision-making' prior to treatment. The aim of this process is to create a trusting relationship that will allow dentists to pinpoint individual needs and raise their patients' knowledge of underlying pathologies to a level enabling them to make informed decisions related to their own health. Patient decision aids (PDAs) can be used to support shared decision-making. PDAs are believed to increase the effectiveness of communication between dentists and patients, thus optimizing patient information and patient care even further. PDAs are designed to inform about clinical problems and outcome probabilities in an easy-to-grasp fashion, usually with examples for illustration, in an effort to make sure that treatment decisions are consistent with personal values. In practice, however, patients are faced with a variety of decision requirements in dental offices, and one-on-one consultations for prosthetic treatment, in particular, will commonly include a wealth of information and treatment options to be discussed. Despite an everyday need for shared decision-making in dentistry, the PDAs which are routinely used to support the oral conversations during consultation visits are not well investigated.

Who can participate?
Patients aged ≥ 20 years old who need prosthodontic treatment

What does the study involve?
This study focused on the patient satisfaction of two different PDAs in prosthodontic consultation. Furthermore, the researchers are interested in how the patients rate the consultation as an adequately intelligible, comprehensive explanation of the treatment steps.

The study involves the usual one-to-one consultation with a dentist and in addition, two different PDAs were used. One PDA is paper-based and the other PDA is computer-based. After these consultations, all patients are asked to complete a questionnaire. Participants should plan approximately one hour of additional time for the consultation.

What are the possible benefits and risks of participating?
Being a study participant enables patients to gain a deeper insight into the possible treatment options for their individual baseline situation and subsequently make more informed decisions about their own health. At the same time, they help to better understand how dental consulations should be designed to be better understood by medical laypeople. There are no harms or risks for the patients who join the study.

Where is the study run from?
The Center for Dentistry and Oral Medicine (Carolinum), Goethe University Frankfurt (Germany)

When is the study starting and how long is it expected to run for?
January 2014 to January 2020

Who is funding the study?
Goethe University Frankfurt (Germany)

Who is the main contact?
Dr Silvia Brandt, hajjaj@med.uni-frankfurt.de (Germany)

Contact information

Type(s)
Principal investigator

Contact name
Dr Silvia PD Brandt

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
29042015

Study information

Scientific Title
Impact of two different patient decision aids in prosthodontic consultations: a prospective randomized clinical study

Study objectives
As null hypotheses, it was assumed that statistical differences in patient ratings would be observable neither (i) for both PDAs versus shared decision-making by oral conversation only; nor (ii) between consultations supported by either of both PDAs.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/05/2014, Ethics committee Goethe University Frankfurt (Theodor-Stern-Kai 7, Frankfurt, 60596, Germany; +49 (0)6963017239; ethikkommission@kgu.de), ref: 71/14

Study design
Prospective randomized clinical study

Primary study design
Interventional

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Increasing the understanding of patients in a prosthetic consultation in order to realise the shared decision making process

Interventions
Patients are prospectively included and randomized to either a control group involving no consultation aids except intraoral findings and radiographs (no PDA); a test group 1 involving the use of a loose-leaf publication in a cardboard box (paper-based PDA); and a test group 2 involving on-screen demonstrations (software-based PDA). Each patient is then asked to rate the consultation on a questionnaire, six key items of which will be analyzed for this study.

Intervention Type
Behavioural

Primary outcome(s)
Patient satisfaction measured using a Likert scale in a questionnaire after prosthodontic consultations

Key secondary outcome(s))

Overall time for prosthodontic consultations measured using a timekeeper during the consultations process

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Patients in need of dental prosthetic treatment
2. Appointment for treatment planned in the dental clinic
3. Aged ≥20 years old
4. Adequate command of spoken and written German
5. Informed consent to participating in the study
6. Recent (≤ 6 months) radiographic documentation available

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
20 years

Sex
All

Total final enrolment
75

Key exclusion criteria
1. Patients with no need for dental prosthetic treatment
2. Pregnant women
3. Patients with a record of drug or alcohol abuse
4. Patients with known allergies to dental materials
5. No appointment for treatment planning in the dental clinic
6. Aged <20 years old
7. No adequate command of spoken and written German
8. No consent to participating in the study
9. No recent (≤6 months) radiographic documentation was available

Date of first enrolment
01/06/2017

Date of final enrolment

01/10/2019

Locations

Countries of recruitment
Germany

Study participating centre
Goethe University Frankfurt
Department of Prosthodontics Center for Dentistry and Oral Medicine (Carolinum)
Theodor-Stern-Kai 7, Building 29
Frankfurt am Main
Germany
60596

Sponsor information

Organisation
Goethe University Frankfurt

ROR
https://ror.org/04cvxnb49

Funder(s)

Funder type
University/education

Funder Name
Goethe-Universität Frankfurt am Main

Alternative Name(s)
Goethe University Frankfurt am Main, Goethe-Universität, Goethe-Universität Frankfurt

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study will be available upon request from Dr Silvia Brandt (brandt@med.uni-frankfurt.de). The following data will be shared on request: the original questionnaire and the pseudonymised analyses. Timing for availability: after request the data can be provided within 1 week from the PI. Each participant gave their personal approval to join the study after being informed about the study procedure. The data was forwarded in pseudonymised form to the initiator of the study for the purpose of scientific evaluation. Only the responsible persons in the respective study centre have access to the personal data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/11/2023	28/11/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes