

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

<b>Submission date</b> 26/07/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/11/2023	<b>Condition category</b> Other	<input type="checkbox"/> 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  $\geq 20$  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 consultations 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

### EudraCT/CTIS number

Nil known

### IRAS number

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Dental clinic

**Study type(s)**

Other, Quality of life

**Participant information sheet**

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

**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 measure**

Patient satisfaction measured using a Likert scale in a questionnaire after prosthodontic consultations

**Secondary outcome measures**

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

**Overall study start date**

01/01/2014

**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  $\geq 20$  years old
4. Adequate command of spoken and written German
5. Informed consent to participating in the study
6. Recent ( $\leq 6$  months) radiographic documentation available

**Participant type(s)**

Patient

**Age group**

Mixed

**Lower age limit**

20 Years

**Sex**

Both

**Target number of participants**

75

**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 ( $\leq 6$  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

**Sponsor details**

Theodor-Stern-Kai 7, Haus 1, 2. OG, Zimmer 207-211

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Germany

60590

+49 (0)69 63017239

ethikkommission@kgu.de

**Sponsor type**

University/education

**Website**

<https://www.uni-frankfurt.de/de?locale=de>

**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**

### **Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

### **Intention to publish date**

30/07/2023

### **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](mailto: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?
<a href="#">Results article</a>		27/11/2023	28/11/2023	Yes	No