Aus der Klinik für Psychiatrie und Psychotherapie der Medizinischen Fakultät Charité – Universitätsmedizin Berlin

DISSERTATION

Evaluation of flexible and integrative psychiatric treatment according to § 64b SGB V in Germany A Mixed Methods staff-oriented exploratory study

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Index of abbreviations

α Cronbach's alpha

p p-value

 χ^2 Chi-square

BPflV Bundespflegesatzverordnung

EX Evaluation
EX Experience

FAÄ Fragebogen zur Arbeitssituation von Ärzten

FAPP Fragebogen zur Arbeitssituation des Pflegepersonals

FIT64b Flexible and Integrative Treatment according to § 64b SGB V

FIT64b-SC FIT64b-specific component

GSI Global Severity Index

GTB Global Treatment Budget

GTM Grounded Theory Methodology

HONOS Health of the Nation Outcome Scale

N Total sample size

n Subsample size

MDK Medizinischer Dienst der Krankenkassen

MVZ Medizinisches Versorgungszentrum

PIA Psychiatrische Institutsambulanz

RN4CAST Registered Nurses Forecast

RPB Regional Psychiatry Budget

SEPICC Scale for Evaluation of Psychiatric Integrative and Continuous Care

SGB Sozialgesetzbuch

SPSS Statistical Package for the Social Sciences

Abstract in English

Background: Flexible and integrative treatment, according to § 64b SGB V (FIT64b), has been implemented on an experimental basis in Germany since the year 2013. The current 23 FIT64b projects aim to support cross-sectoral and need-adapted treatment for people with mental disturbances on the financial basis of a "Global Treatment Budget". Although evidence supports the importance of staff involvement for successful implementation processes, the staff perspective of FIT64b implementation has not yet been analyzed. The aim of this thesis is thus to study experiences, evaluations, and critical factors for successful FIT64b implementation from the staff perspective.

Methods: Experiences and evaluations of twelve FIT64b projects from the perspective of physicians, psychologists, and nurses were approached between 01.07.2015 and 31.08.2017, using an exploratory Mixed Methods design. This approach was structured using defined and operationalized "FIT64b-specific components" (FIT64b-SCs), which were developed using the Grounded Theory Methodology. FIT64b-SCs address structural and procedural changes that follow FIT64b implementation. In a qualitative study, "core themes" were derived from staff experiences and evaluations by qualitative content analysis, according to Mayring. In a quantitative study, staff experiences and evaluations were analyzed descriptively and using bivariate statistics. Critical factors for successful FIT64b implementation were identified using a logistic regression analysis.

Results: The qualitative results revealed a variety of ways in which FIT64b impacted staff, treatment culture, and ethos, such as increased freedom in therapeutic decisions and a change in the therapeutic attitude for service users. The quantitative results demonstrated that physicians and psychologists were more experienced than nurses with eight out of ten FIT64b-SCs. Overall, the results showed a positive evaluation of FIT64b, while considerably differing between the occupational groups (physicians/psychologists 4.4 out of 5 points, nurses 3.9 out of 5). Critical factors for successful FIT64b implementation from the physicians' and psychologists' perspective were the number of nurses/special therapists per physician/psychologist and the project duration, from the nurses' perspective it were the work conditions. Both groups shared the opportunity to join training programs on the objectives of FIT64b as a factor for successful implementation. These factors together explained 49% of the variance for physicians'/psychologists' evaluations and 34% of those of nurses.

Implications: Results illustrate the importance of integrating the staff perspective into FIT64b research and implementation. The implementation process should be modified by establishing training programs on FIT64b objectives and the recognition of different needs of the occupational groups. The exploratory findings require validation through prospective and longitudinal observation.

Kurzfassung in deutscher Sprache

Hintergrund: Seit dem Jahr 2013 werden Projekte nach § 64b SGB V (FIT64b) in Deutschland modellhaft implementiert. Das Ziel der aktuell 23 FIT64b Projekte ist die Förderung sektorübergreifender und bedarfsadaptierter Versorgung von Menschen mit psychischen Störungen auf finanzieller Basis eines "Global Treatments Budgets" (Globales Behandlungsbudget). Im Gegensatz zu der nachgewiesenen Bedeutung einer Beteiligung von Mitarbeitenden für erfolgreiche Implementierungsprozesse, wurde die Perspektive der Mitarbeitenden auf die Implementierung von FIT64b bislang nicht untersucht. Ziel dieser Arbeit ist es daher, Erfahrungen, Bewertungen und Erfolgsfaktoren der FIT64b Implementierung aus der Mitarbeitendenperspektive zu untersuchen.

Methodik: Erfahrungen und Bewertungen von FIT64b Projekten aus der Perspektive von Ärzt*innen, Psycholog*innen und Pflegenden aus zwölf FIT64b Projekten wurden zwischen dem 01.07.2015 und dem 31.08.2017 anhand eines Mixed Methods Designs untersucht. Dieser Ansatz wurde anhand definierter und operationalisierter "FIT64b-spezifischer Komponenten" (FIT64b-SCs) strukturiert, die mittels Grounded Theory Methodologie entwickelt wurden. FIT64b-SCs beschreiben strukturelle und prozessuale Veränderungen in Folge der FIT64b Implementierung. Im Rahmen einer qualitativen Studie wurden sogenannte "core themes" (Kernthemen), basierend auf Erfahrungen und Bewertungen von Mitarbeitenden, mittels qualitativer Inhaltsanalyse nach Mayring herausgearbeitet. Im Rahmen einer quantitativen Studie wurden Erfahrungen und Bewertungen der Mitarbeitenden deskriptiv und bivariat analysiert. Erfolgsfaktoren für die Implementierung von FIT64b Projekten wurden mittels logistischer Regressionsanalyse ermittelt.

Ergebnisse: Qualitative Ergebnisse illustrierten verschiedene Einflüsse der FIT64b Implementierung auf Mitarbeitende, deren Haltung sowie die Behandlungskultur. Beispiele hierfür sind größere Freiräume hinsichtlich therapeutischer Entscheidungen und eine veränderte therapeutische Haltung gegenüber Angebotsnutzenden. Quantitative Ergebnisse zeigten eine größere Erfahrung von Ärzt*innen und Psycholog*innen bei acht von zehn FIT64b-SCs im Vergleich mit Pflegenden. Insgesamt zeigten sich positive Bewertungen von FIT64b Projekten, jedoch mit deutlichen Unterschieden zwischen den Berufsgruppen (Ärzt*innen/Psycholog*innen 4,4 von 5 Punkten, Pflegende 3,9 von 5). Erfolgsfaktoren der Implementierung aus der Perspektive von Ärzt*innen und Psycholog*innen waren die Anzahl von Pflegenden/Spezialtherapeut*innen pro Ärzt*in und Psycholog*in und die Projektdauer, aus Sicht der Pflegenden waren es die Arbeitsbedingungen. Erfolgsfaktor aus der Perspektive beider Gruppen war die Möglichkeit, an Schulungsprogrammen bezüglich der Ziele von FIT64b teilzunehmen. Zusammengenommen erklärten diese Faktoren 49% der Varianz der Bewertungen von Ärzt*innen und Psycholog*innen sowie 34% derer von Pflegenden.

Implikationen: Die Ergebnisse veranschaulichen die Bedeutung der Integration der Mitarbeitendenperspektive in Forschungsvorhaben und in der Implementierung von FIT64b Modellprojekten. Eine Modifikation des Implementierungsprozesses mit der Etablierung von Schulungsprogrammen zu den Zielen von FIT64b sowie die Berücksichtigung verschiedener Bedürfnisse der Berufsgruppen erscheinen für weitere Implementierungsvorhaben notwendig. Die explorativen Ergebnisse bedürfen der Validierung durch prospektive und Längsschnittstudien.

1. Introduction

1.1 Background and problem statement

Empirical knowledge indicates a gap between the positive effects of flexible and integrative treatment. according to § 64b SGB V2 (FIT64b), as the reduction of inpatient treatment, an increase of day and outpatient treatment capacity, a reduced duration of sick leave [1-4], service user³ satisfaction [2], and its practical application [5]. Currently, less than 5% of the roughly 450 supply regions in Germany offer FIT64b, as its (currently experimental) implementation, is hindered by barriers such as a lack of testability and reversibility, as well as lacking compatibility with simultaneous standard care and the resultant high perceived risk for service providers [5]. Progress towards a broader implementation of integrative treatment is limited, as the German mental healthcare system is characterized by a pervasive fragmentation of its treatment settings⁴ and healthcare sectors⁵. Current reimbursement practices for psychiatric services do not incentivize the integration of these settings and sectors [6-10]. Instead, hospital-based psychiatric treatment in Germany rests on a day and performance-oriented reimbursement system, with separated budgets for in-patient and day-patient treatment and budgets for psychiatric out-patient treatment (Psychiatrische Institutsambulanz, PIA). This makes it difficult to structurally and functionally connect these budgets in a therapeutically and economically useful way [11, 12]. This lack of integration does not satisfy the treatment requirements for chronically ill and multi-morbid people with mental disturbances as the treatment for many of them requires a flexible combination of settings, sectors, and services, who often operate formally and legally independently [6, 13-16]. These structural insufficiencies may indeed result in over and underutilization or misguided incentives for healthcare services, such as the maximizing of inpatient occupancy [9, 17, 18]. Further, the current structures may build a barrier for chronically ill and multi-morbid people with mental disturbances to access need-adapted treatment, as well as participation and inclusion in society [6, 14, 17].

¹ According to the definition by Kodner and Spreeuwenberg (2002), the term "integration" is understood as "a coherent set of methods and models on the funding, administrative, organizational, service delivery, and clinical levels, designed to create connectivity, alignment and collaboration within and between the cure and care sectors" [16:3].

² SGB V = German Social Code Book V.

³ The term "service user" is used in this thesis instead of the term "patient" whenever it is not otherwise required due to an established term as "in-patient treatment", or others.

⁴ The term "setting" is understood in this thesis as the intra-organizational arrangement of in-patient, day-patient, and out-patient treatment.

⁵ The German health care system is divided into sectors for out-/day-patient and in-patient treatment, rehabilitation, integration assistance, and social welfare [5, 107, 108].

Overcoming this fragmentation is deemed a major challenge for the German healthcare and social services system [5, 17, 19]. Low-threshold and cross-sectoral services with continuity of the treatment team are demanded to improve this state of affairs [20, 21]. Several legislations, aiming to change the situation, have been introduced by the German Social Code, such as "Integrated Care", "Disease Management", "Medical Care Centers" (Medizinisches Versorgungszentrum, MVZ), and the "Regional Psychiatry Budget" (RPB) [2, 5]. Without underrating from the importance of one of these individual approaches, this thesis focuses on the evaluation of FIT64b, as a successor model of the RPB [22].

After several years of implementing single RPBs on the basis of individual contracts for capitation payment⁶, the debate around alternative financial incentives in form of a budget-based accounting mode was actualized by a legislative reform (§ 64b SGB V) [23]. Since the year 2012, this reform has allowed for the nationwide experimental implementation of FIT64b by enabling accounting on the basis of a "Global Treatment Budget", as described in section 1.2 [1, 24, 25]. Presently, the question has arisen as to whether FIT64b should become a regular part of the German mental healthcare system. After the current trial period, the German government will decide on this question in the year 2024.

Present findings about FIT64b, consisting of data from statutory health insurance funds ("EVA64" study) [1, 3, 4], for service users, as well as individual findings for informal caregivers and staff ("EvaMod64b" study) [2, 25] are not sufficient for understanding the FIT64b implementation process from the staff perspective⁷. This research gap contradicts the documented importance of staff involvement for successful implementation processes [24, 26-31].

In this thesis, Mixed Methods research shall be guided by defined and operationalized "FIT64b-specific components" (FIT64b-SCs), making the heterogeneous FIT64b projects comparable to each other and building a framework for linking the qualitative and the quantitative study of the thesis, such as by the development of research questions and instruments (study 1). Based on these components, the aim of this thesis is to qualitatively (study 2) and quantitatively (study 3) survey experiences, evaluations, and critical factors for successful FIT64b implementation from the staff perspective. This thesis evolved from the Mixed Methods exploratory study "EvaMod64b", which aimed to describe the experiences and evaluations of twelve FIT64b projects from the perspective of service users, informal caregivers, and staff, as well as the degree of implementation for each project [2, 32].

⁶ Capitation payment is a form of a budget-based accounting mode, which will be defined in section 1.2 in footnote 10.

⁷ The term "staff" relates to therapeutic staff (physicians, psychologists, nurses, and special therapists, such as occupational therapists, music therapists, and art therapists).

1.2 Flexible and integrative treatment according to § 64b SGB V

Since the year 2012⁸, a legislative reform (§ 64b SGB V) allowed for a nationwide FIT64b implementation on an experimental basis, being limited to a maximum duration of 15 years [2, 23, 33]. The legislation's objective is to encourage care advancement for people with mental disturbances by aiming to improve service users' or cross-sectoral care in clinic and home environments [23]. The legal framework of § 64b SGB V does not define a treatment model [25]. This aspect results in a heterogeneity of structures and procedures between the implemented FIT64b projects, making it difficult to compare them to each other [2, 4, 15, 34]. For example, some FIT64b departments include service users from each health insurance company while others did not.

FIT64b projects are financed by a "Global Treatment Budget" (GTB) as a project-based fixed budget. The budget is annually allocated, and is meant to cover all forms of department-based psychiatric treatment for a defined population [1, 15, 24, 25]. Health insurance companies and service providers negotiate the GTB on the basis of the historical expenditure, and the number of service users treated in the years prior to the contract (top-down computation with a ± 6% corridor) [15]. According to this funding approach, the GTB can be understood to combine the ideas of block contracts and capitation payment [24, 25]. This accounting mode leaves sufficient latitude for the FIT64b departments to apply stratified treatments and supply options to the needs of service users and regional peculiarities [35]. The GTB may incentivize cross-sectoral and need-adapted treatment through a more flexible and effective use of resources than standard care, as the budget is not restricted to particular activities or settings [4, 15, 24, 36]. Assessments by the Medical Service of Health Funds (Medizinischer Dienst der Krankenkassen, MDK) are not carried out in the extent as it is known from standard care [5].

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⁸ The § 64b SGB V was introduced in the year 2012. FIT64b projects have been implemented since the year 2013.

⁹ Block contracts are, according to the definition by the British Medical Association (2018), financed by a fixed lump sum, "roughly determined by precedents such as historical expenditures for a particular service, but can be adjusted according to the patient needs. The lump sum is set irrespective of the number of patients treated or the amount of therapeutic engagement that is undertaken" [24:2, 109]. 10 Capitation payment bases on an "annual lump sum for a given number of patients in a target population, irrespective of how many services the patients may receive" [15, 24:2, 110]. It entails uniform remuneration per treated patient (bottom-up computation) [24].

To date, 23 German psychiatric departments have introduced FIT64b [25]. Several of the present FIT64b build upon RPB projects [37]. Between the years 2003 and 2012, these RPB projects had been implemented in single psychiatric departments on the basis of individually conducted contracts between service providers and health insurances, according to § 26 of the former Federal Hospital Refund Regulation (Bundespflegesatzverordnung, BPflV). As already mentioned, RPB projects had been funded by capitation payment. They included service users of a defined region independent of their diagnosis and, in contrast to FIT64b, also independent of their health insurance company [18, 22, 39, 43]. In the year 2013, all these contracts were transferred into the framework conditions following § 64b SGB V. Historically and textually, there were notable consistencies between both of the contractual models for concrete restructuring processes [37]. It is thus important for this thesis to include knowledge from the RPB to form a body of evidence for FIT64b.

1.3 The present research

To date, intermediate results for FIT64b from the ongoing standardized evaluation study "Eva64" [1, 3, 4], based on health insurance data from 13 FIT64b, and results from the finalized Mixed Methods exploratory study "EvaMod64b" [2] of twelve FIT64b projects are available. Present findings indicate an increase in care efficacy for most¹¹ of the present FIT64b projects when compared to standard care by outcome parameters as the reduction of inpatient treatment (treatment capacity and length of stay), an increase in day and outpatient treatment capacity, and a reduced duration in sick leave [1-4]. Whereas, projects facilitating a stronger cooperation across sectors are rare [14, 38]. Experiences and evaluations of service users were overall positive and significantly increased with the degree of FIT64b implementation [2]. Clinical parameters as service users' level of functioning or the development of psychopathology and health status are currently lacking for FIT64b. The evidence for this aspect stems from RPB research.

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¹¹ Study results showed a variable effectiveness in FIT64b projects [1-4]. According to the reduction of fully-inpatient treatment, Neumann et al. (2019) found more effective care for eleven FIT64b projects, a reduction of days of sick leave for nine projects and cheaper care for seven projects in their standardized evaluation study of 13 FIT64b projects [3]. Baum et al. (2020) found, by their claims-data-based meta-analysis of 13 controlled studies, better outcomes in terms of the reduction of inpatient treatment and a reduced duration of sick leave for departments with FIT64b-like contracts/environments existent prior to the initialization of FIT64b when compared to departments without preexisting FIT64b-like environments [1].

an improved level of functioning [12, 22, 35, 39, 40], while psychopathology¹³ seems to develop comparably under the RPB and standard care, or partly worse for service users diagnosed with mental and behavioral disturbance related to alcohol [12, 39, 40]. In a pre-post comparison by secondary data analysis, socio-demographic and clinical indicators of health status (legal form of admission, suicidal tendency, housing and working situation, global estimation of response at discharge based on psychiatric assessment) and social adjustment significantly improved under RPB conditions [35]. In contrast to the availability of these (partly intermediate) findings, results capturing the perspective of staff as those who carry out most of the structural and organizational changes following FIT64b implementation are lacking. The only available empirical knowledge on a budget-based accounting mode stems from a pre-post comparison by secondary data analysis of the RPB, providing single descriptive staff-related structural data [41]. Two other research projects on the RPB only gave short textual progress reports about the staff perspective without publishing data [42, 43]. In the pre-post comparison, no indications for work intensification in terms of increased overtime for nurses were found, but a slight decrease in the amount of full-time employed nurses (55.68 to 55.32) when compared to other occupational groups (+2.39 for physicians/psychologists, +1.89 for occupational therapists) [41]. A decreasing trend in overtime may indicate that the operating nursing activities may not have been affected by further and continuing education or other implementationrelated activities. The reason for the drastic increase in sick days (from 639 to 962) remained unclear. Because of the rare and only descriptive findings illustrating the staff perspective for a budget-based accounting mode, this thesis aims to study experiences, evaluations, and critical factors for successful FIT64b implementation from the staff perspective.

Results for the RPB indicate increased but diagnosis-related care efficacy¹², in terms of stable costs and

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¹² Based on three prospective controlled studies and a systematic literature review, following diagnose-related effects were found: While found to be at least cost-neutral, the RPB seems to facilitate the treatment (in terms of level of functioning) of service users diagnosed with schizophrenia, schizotypal and delusional disturbances and partly for service users diagnosed with affective disturbances, though not for service users diagnosed with mental and behavioral disturbance related to alcohol compared to a control region [12, 22, 39, 40].

¹³ For psychopathology, no differences between a model region and a control region were found in two prospective controlled cohort studies [12, 39]. Another prospective controlled cohort study found a significant statistical (but clinically questionable) improvement in psychopathology (measured by the Global Severity Index, GSI), whereas the objective burden of symptoms (measured by the Health of the Nation Outcome Scale, HONOS) developed more poorly for service users diagnosed with mental and behavioral disturbance related to alcohol [40].

1.4 The importance of staff experiences and evaluations for the implementation of FIT64b

The quote "organizations do not behave, people do" [44:7] illustrates the role of staff, with professional attitudes, traits, and other aspects as active agents in organizational development [45]. While several staff-related aspects may have an influence on FIT64b implementation, this thesis focuses on staff attitudes. For studying the role of staff attitudes to FIT64b implementation, staff experiences and evaluations of structural and organizational changes constitute a critical factor for implementation, service, especially for FIT64b as personal as it is understood [24, 26-31]. According to the definition of personal services, the outcome quality of FIT64b projects reflects the interactions between service users and staff, implicitly and explicitly communicating their attitudes towards workplace modifications [24, 46-48]. Based on these assumptions, defining a new treatment concept top down may be limited by the fact that a concept is only manifested through people acting towards it, or in other words, as cited above, "behaving" towards it [44, 49]. A theme like 'we are doing a model project now' thus needs to be 'brought to life' such as by systematic implementation under recognition and integration of the staff attitudes. Therefore, the understanding of staff attitudes towards FIT64b is a relevant factor for the evaluation of FIT64b implementation processes [24, 26, 28, 30, 46, 47, 50]. In this thesis, "experiences" are understood as describing "whether staff members were informed about FIT64b-related structural and procedural changes and to what extent they experienced these in their occupational routine" [24:4]. Furthermore, the FIT64b implementation depends on staff evaluations and whether staff identify with the objectives of FIT64b, integrate them into professional attitudes and daily work procedures, or whether resistance against structural and procedural changes may occur [24]. "Evaluations" are understood as illustrating the attitudes towards and identification with the changes experienced [24]. Resistance to change may be caused by a potential loss of status or habits [51], or unawareness and a lack of understanding of the usefulness of the innovation [52-57].

As psychiatry and psychotherapy are traditionally areas which require interprofessional cooperation, it is important to understand and differentiate between the attitudes of occupational groups as represented in this work by physicians, psychologists, and nurses, as the three largest occupational groups in psychiatry and psychotherapy. Different and possibly opposing attitudes may lead to different implicit and explicit communication, which is important to perceive, as it may hinder implementation [24]. of Based on these assumptions, a bottom-up strategy measuring experiences and evaluations of staff is applied in this thesis. The aim of this thesis is to study experiences, evaluations, and critical factors for successful FIT64b implementation from the staff perspective. This aim is operationalized by four research questions, as presented in the following.

1.5 Aims of the thesis and derivation of research questions

Despite sharing common overarching aims, the heterogeneity of FIT64b makes it difficult to compare the projects to each other, and therefore limits their assessability for research [4, 15, 32, 54]. As international literature defining specific impact mechanisms of flexible and integrative treatment is not applicable due to the specifics of Germany's health care system [54, 55], the first subject of the thesis was to define and operationalize common impact mechanisms of FIT64b in the form of "FIT64bsepcific components" (FIT64b-SCs). These components shall address the main changes that follow question is 54]. The first research implementation [32, thus formulated: (1) Might project overarching FIT64b-SCs describe structural and procedural changes that follow FIT64b implementation from a staff perspective? As FIT64b is a complex intervention, its evaluation requires a Mixed Methods and multi-phase assessment approach [2, 56]. FIT64b-SCs may build a framework for linking the qualitative and the quantitative study of the thesis, such as by the development of research questions, instruments, and the integration of results. Based on the above distinction of staff experiences and evaluations of FIT64b-related structures and procedures, the second subject of research was to qualitatively and quantitatively approach these experiences and evaluations. Research question two is thus formulated: (2) How are FIT64b-SCs experienced and evaluated by staff? The third subject of research was to derive critical factors for successful FIT64b implementation from staff evaluations. Thereby, it would be possible to draw conclusions for which individual, structural, and organizational aspects are linked to the perspective of staff. This may allow for insights into the mechanisms of implementation from the staff perspective, which may guide the generating of hypotheses for subsequent confirmatory research. Following research question three is thus formulated: (3) What are the critical factors for successful FIT64b implementation from the staff perspective? Subject four was to survey possible differences between the groups¹⁴, based on the above formulated need for differentiation between experiences and evaluations of occupational groups in psychiatry and psychotherapy. Research question four is thus formulated: (4) Are there differences between the occupational groups regarding experiences and evaluations?

These four research questions were approached by three studies. In study 1, FIT64b-SCs were defined and operationalized. Study 2 aimed to qualitatively approach how the implementation of FIT64b-SCs is experienced and evaluated by staff, referred to as "core themes". Study 3 aimed to quantitatively approach how FIT64b-SCs are experienced and evaluated by staff and to derive critical factors for successful implementation from evaluations of staff.

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¹⁴ For reasons of space, physicians and psychologists are defined as one group in this thesis. This should not underrate possible differences between these occupational groups.

2. Material and methods

In the next sections, the thesis' research procedure, as part of the "EvaMod64b" study, is presented (2.1), followed by section 2.2, reporting the contribution of the three studies of this thesis to answering the research questions.

2.1 The thesis' research procedure as part of the study "EvaMod64b"

This thesis resulted from the multi-center and Mixed Methods exploratory study "EvaMod64b", which aimed to describe the experiences and evaluations of twelve FIT64b projects across Germany from the perspectives of staff, service users, and informal caregivers, as well as the degree of implementation for each project [2, 32]. The study was financed by the participating FIT64b departments and realized by the Medizinische Hochschule Brandenburg, the Charité Universitätsmedizin Berlin, the Kompetenzzentrum für Klinische Studien Bremen, and the Forschungsinstitut SOCIUM in Bremen, between 01.07.2015 and 31.8.2017. The study was approved by the Ethics Committee Brandenburg [2016, No. S 7 (a)], according to the ethical standards of the Declaration of Helsinki and later amendments [2].

Between the years 2015 and 2016, all then-established FIT64b projects from 15 psychiatry departments in nine different German cities and regions were invited to participate in the study [2, 24]. From these, 13 departments agreed to participate (ten adult psychiatry and three child and adolescent psychiatry departments), located in Schleswig-Holstein (Heide, Itzehoe, Rendsburg/Eckernförde), Saxony (Glauchau), Thuringia (Nordhausen (adult psychiatry, child and adolescent psychiatry)), Lower Saxony (Lüneburg), Hessen (Riedstadt (adult psychiatry, child and adolescent psychiatry)), Berlin (the Kreuzberg, Neukölln and Friedrichshain districts (adult psychiatry, child and adolescent psychiatry)), and Brandenburg (Rüdersdorf). For organizational reasons, one of these 13 departments withdrew from the study [2, 24].

Project starts were from January 2013 to January 2016. FIT64b departments differed in their starting conditions: at the time of data collection, the project duration of eight departments was under two years, the other four departments' project duration was under or equal to two years. Seven departments had a history of flexible and integrative treatment in the form of individually negotiated contracts with health insurance companies. Departments were either public (seven departments) or non-profit (five departments), and provided care for regional populations ranging from 85,000 to 425,000 people. Eight departments were under contract with all national insurance companies. In the four departments that had contracts with only one or two insurers, not all service users received treatment according to § 64b SGB V [24, 54].

2.2 The three studies of the thesis

In the following, each of the three studies forming this thesis is presented by the aspects 'study design and participants', 'outcome measures', and 'data analysis'. Some information has been added to this section which cannot be found in the print versions of the studies. The print versions can be found in the annex. The results of the studies are presented in section 3.

Study 1 - von Peter S, Ignatyev Y, Indefrey S, Johne J, Schwarz J, Timm J, Heinze M. Spezifische Merkmale zur Einstufung der Modellversorgung nach § 64b SGB V. Nervenarzt, 2018; 89(5):559-564.

Study design and participants. Based on the Grounded Theory Methodology (GTM), a semi-structured qualitative survey of staff members' (n = 24), service users' (n = 16), and informal caregivers' (n = 4) experiences and evaluations of FIT64b from twelve FIT64b departments took place between September and October 2015 in two phases [32]. Each department was visited for two days. Inclusion criteria were being over 18 years of age, having the ability to read and understand German, and the capacity to provide informed consent. Service users were excluded if they had an acute mental disturbance, a severe mental disability, or if their admission to the department was involuntary [2]. According to the GTM, sampling was theory-based and sequentially structured [57], balancing age, gender, educational level, and different lengths, as well as different intensive experience with FIT64b. Staff with preferably long FIT64b experience from different occupational groups and with different professional expertise were recruited. Informal caregivers were selected with and without reference to the participating service users. As a requirement, all participants had to be informed about FIT64b, and had to know the department before the FIT64b implementation and/or know standard care. A verbal project description was given to potential participants. They were informed about the voluntary nature of participation, that refusal of participation would not affect the quality of their care, and they were guaranteed anonymity. Sampling was continued until data saturation was met [32]. The average duration of interviews and focus groups was 90 minutes. Interviews were recorded in written form and anonymized. Field notes were documented before and after the interviews. Department and FIT64brelated structural data was requested [32].

Outcome measures. FIT64b-SCs were identified via the development of a middle-range theory¹⁵, integrating FIT64b experiences and evaluations from three stakeholder groups, as well as the structural and process variations of FIT64b projects [32, 57]. To assess experiences and evaluations, 14 semi-structured focus groups [58] and 12 semi-structured expert-interviews [59] with staff, service users,

¹⁵ The term "middle-range theory" refers to the terminology of the GTM [57].

and informal caregivers were conducted. The interview guideline entailed experienced changes on several levels following the FIT64b implementation for day-to-day treatment and professional routine, the benefits and disadvantages of FIT64b in comparison to standard care, and experienced treatment quality [32]. Expert-interviews also included questions about structural and procedural peculiarities of the model projects, quality objectives, and FIT64-related changes of treatment pathways and workflows [32]. Department and FIT64b-related structural data was assessed via a standardized questionnaire.

<u>Data analysis.</u> The development of the middle-range theory, in terms of FIT64b-SCs, followed a complex, multi-step and iterative process, according to the GTM [32, 57]. A GTM-typical alternating inductive-deductive procedure, integrating an international literature search and department and FIT64b-related structural data was employed to gain and operationalize the components. Operationalization was discussed within a steering committee (research team, staff from different occupational groups, service users, and informal caregivers) and continuously modified, in the manner of iterative theory development. The results of one department were alternately presented to another department and discussed, qualitatively evaluating content validity and the practicability of the components. During the course of the research project, operationalization was improved several times, though a fundamental revision of the FIT64b-SCs was not required. Open coding was thus followed by an axial and a selective coding strategy¹⁶ [32]. All the steps of the analysis were carried out manually.

Study 2 - Schwarz J, Galbusera L, Bechdolf A, Birker T, Deister A, Duve A, Heiser P, Hojes K, Indefrey S, Johne J, Rehr B, Rout S, Scherk H, Schulz-Du Bois A, Wilms B, Zedlick D, Zeipert M, Heinze M, von Peter S. Changes in German Mental Health Care by Implementing a Global Treatment Budget — A Mixed-Method Process Evaluation Study. Front. Psychiatry, 2020; 11:426.

Study design and participants. Based on a qualitative approach, a semi-structured qualitative survey of staff members' (n = 138), service users' (n = 63), and informal caregivers' (n = 35) experiences and evaluations of FIT64b from 10 FIT64b departments took place between April and October 2016 [25]. Potential participants were purposely selected, according to a sampling plan [25]. Each department was visited for two or three days. Inclusion criteria were being over 18 years of age, having theh ability to read and understand German, and the capacity to provide informed consent. Service users were excluded if they had an acute mental disturbance, a severe mental disability, or if their admission to the department was involuntary [2]. In addition to the sampling plan of study 1, a balance in expertise for the different fields of the interview guideline (see below) was taken into consideration. Sampling and data collection were performed in all departments until theoretical saturation was met [25]. The average

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¹⁶ The terms of this different coding strategies refers to the terminology of the GTM [57].

duration of the interviews and focus groups was 84 minutes. A verbal project description was given to potential participants. They were informed about the voluntary nature of participation, that refusal of participation would not affect the quality of their care, and they were guaranteed anonymity. Interviews were recorded digitally, transcribed verbatim, and anonymized. Department and FIT64b-related structural data, as well as semi-quantitative data, was requested [25].

Outcome measures. To assess FIT64b experiences and evaluations in terms of "core themes", 31 semi-structured focus groups [58] (2-5 in each department) and 15 semi-structured expert-interviews [59] (1-3 in each department) with staff, service users, and informal caregivers were conducted [25]. The interview guideline entailed eleven fields, according to the eleven FIT64b-SCs [25]. In expert-interviews, additional semi-quantitative data was collected about the structural and procedural peculiarities of the model projects, quality objectives, and FIT64-related changes of treatment pathways and workflows [25]. Department and FIT64b-related structural data was assessed using a standardized questionnaire [25].

Data analysis. Using qualitative content analysis, according to Mayring [60], emerging core themes were mapped into a diagram following the German Throughput Model by Pfaff and Schrappe, depicting the FIT64b implementation process from its inputs to its outcomes [25, 61, 62]. The qualitative material was analyzed separately for each of the three groups of participants. During content analysis, qualitative material was assigned to the FIT64b-SCs as deductive major categories [25]. Requirements for FIT64b implementation were analyzed, and further subcategories developed [25]. Due to the large volume of data the diagram was reduced, and only the FIT64b-SCs were left (I, II, III, IV) which showed the highest data density. Department and FIT64b-related structural data, as well as semi-quantitative data, was used to illustrate variations in the departments' implementation processes [25]. During this process, the quality of the analysis was ensured through continuous discussions between paired researchers and analytical workshops ("Forschungswerkstatt") to triangulate and validate the results [25]. All the steps of the analysis were carried out manually.

Study 3 - Indefrey S, Braun B, von Peter S, Bechdolf A, Birker T, Duve A, Hardt O, Heiser P, Hojes K, Rehr B, Scherk H, Schulz-Du Bois AC, Wilms B, Heinze M. Implementation of a global treatment budget in psychiatric departments in Germany – results and critical factors for success from the staff perspective. Front. Psychiatry, 2020; 11:610.

Study design and participants. Based on an exploratory study design, a standardized written survey of physicians (n = 127), psychologists (n = 84), nurses (n = 352), and special therapists (n = 132) from twelve FIT64b departments took place between October 2016 and February 2017 [2, 24]. FIT64b experiences and evaluations, sociodemographic, professional, and structural characteristics of staff and workplaces, as well as work conditions were requested. The survey's questionnaire, which consisted of 94 items for nurses and 85 for physicians/psychologists, was administered in a pencil and paper format which required 15-20 minutes to complete [24]. The study was approved by the respective institutional work councils. Potential participants were informed about the survey in several workplace meetings. Only staff members working in settings with partial or complete FIT64b implementation were recruited for the study. A verbal project description was given to potential participants. They were informed about the voluntary nature of participation and were guaranteed anonymity [24].

Outcome measures. Staff experiences and evaluations, defined as a measure of the degree of FIT64b implementation in this study, were assessed by the two metrics "Experiences" (EX) and "Evaluations" (EV). EX and EV were measured by the 28-item questionnaire "Characteristics, Structures and Procedures of Model Projects", which was specifically developed for this study [24]. The FIT64b-SC "accessibility of services" was not part of the questionnaire, as it was inapplicable for staff [24]. Thus, EX and EV of ten from totally eleven FIT64b-SCs, each defined by one main and one or more subordinate categories, were measured in this study [24]. In this questionnaire with a oneanswer scale with two subsections, following key question was posed: "How do you rate the impact of structures/procedures for the treatment/care for patients with mental illness in your hospital such as are already partially realized/enabled by FIT on the outcomes of your occupational routine in the past months?" In the first part, measuring EX, permitted responses were "nonexistent" and "present, but not yet assessable". In the second part, measuring EV, permitted responses were "present and assessable and my opinion of it is (...)" "very positive", "rather positive", "partly", "rather negative", and "very negative". Sociodemographic, professional, and structural characteristics of staff and workplaces were requested (29 items for physicians/psychologists, 34 for nurses). Work conditions were measured by the German "Fragebogen zur Arbeitssituation von Ärzten" (FAÄ) (28 items) [63] and the German "Fragebogen zur Arbeitssituation des Pflegepersonals" (FAPP) [64, 65] (32 items), as well as by five questions from the study "RN4CAST" ("Registered Nurses Forecast") [24, 66].

<u>Data analysis</u>. Because of the heterogeneity of special therapists' professional backgrounds and fields of activities, only data from physicians and psychologists (as one group), as well as from nurses was analyzed [24]. The statistical analysis of EX and EV covered the ten main categories of the 28-item

questionnaire "Characteristics, Structures and Procedures of Model Projects". Staff members' sociodemographic and professional characteristics, their ratings of organizational and structural characteristics of FIT64b departments, as well as EX and EV were analyzed descriptively [24]. Only if EX was rated to be "present and assessable", EV was calculated. Scores of EV ranged from 1 (= low/negative evaluation) to a maximum of 5 (= high/positive evaluation) [24]. To analyze categorical data, the χ^2 -test was performed or, in the case of small cell counts, Fisher's exact test. Correlations between EV and staff members' sociodemographic, professional, as well as their ratings of organizational and structural characteristics of FIT64 departments were analyzed via Spearman correlation [24].

Critical factors for successful FIT64b implementation were identified by a logistic regression analysis. The regression analysis was based on the results of the exploratory Spearman correlations. For this analysis, the EV, as the dependent variable, was dichotomized to 1 = "very negative", "negative", "partly", and 2 = "rather positive", "very positive". For physicians/psychologists, logistic regression analysis was performed with the independent variables "age" (> versus \leq mean), "duration of employment in psychiatry" (> versus \leq mean), "number of nurses/special therapists per physician/psychologist" (> versus \leq median 3.3), "project duration" (\leq 2 years versus > 2 years), "training programs" ("rather positive", "very positive" versus "very negative", "negative", "partly"), and "sum of positively rated work conditions" (\geq versus \leq 50% of work conditions positively rated).

For nurses, logistic regression analysis was calculated with the independent variables "training programs" (dichotomized as above), "sum of positively rated work conditions" (dichotomized as above), "project duration" (dichotomized as above), and "supervisor for other nurses" (being supervisor for other nurses versus no status as supervisor). All research questions were tested exploratory with α of 5% and no use of alpha-adaption. Test results with $p < \alpha$ (5%) were deemed significant. Statistical analysis was performed by SPSS 15 and 22 [24].

3. Results

In this section, for reasons of space, only the main results are reported. The discussion will include details of the studies, which are not presented here.

Results for study 1 – von Peter S, Ignatyev Y, Indefrey S, Johne J, Schwarz J, Timm J, Heinze M. Spezifische Merkmale zur Einstufung der Modellversorgung nach § 64b SGB V. Nervenarzt, 2018; 89(5):559-564.

Sample characteristics. The sample consisted of 24 staff members, 16 service users, and four informal caregivers. $3/4^{17}$ of the participating staff worked directly/clinically within FIT64b conditions, $2/3^{17}$ had a leadership position, and three staff members were from the controlling department. $2/3^{17}$ of service users and informal caregivers were experienced with standard care or with the treatment in the department before the start of the FIT64b project [32, 54]. An adequate distribution of the abovementioned person and disturbance-related aspects was assured via theoretical sampling, according to the GTM [32].

<u>FIT64b-SCs.</u> The following eleven FIT64b-SCs were defined and operationalized: (1) shifting into outpatient setting, (2) flexible care management across settings, (3) continuity of care, (4) multiprofessional cooperation, (5) therapeutic group sessions across settings, (6) outreach home care, (7) involvement of informal caregivers, (8) accessibility of services, (9) sovereign steering of services, (10) cooperation across sectors, and (11) expansion of professional expertise [32]. The definition and operationalization of the components may be found in the print version of study 1 in the annex. Further details regarding the relevance of these components for staff can be found in the sections 4.1 and 4.3.

Results for study 2 – Schwarz J, Galbusera L, Bechdolf A, Birker T, Deister A, Duve A, Heiser P, Hojes K, Indefrey S, Johne J, Rehr B, Rout S, Scherk H, Schulz-Du Bois A, Wilms B, Zedlick D, Zeipert M, Heinze M, von Peter S. Changes in German Mental Health Care by Implementing a Global Treatment Budget — A Mixed-Method Process Evaluation Study. Front. Psychiatry, 2020; 11:426.

<u>Sample characteristics</u>. The sample consisted of 138 staff members, 63 service users, and 35 informal caregivers. 59% of the staff were female, 65% had worked in the department before the introduction of FIT64b. Service users had an average duration of the diagnosed disturbance (mostly various forms of schizophrenia spectrum disturbances) of seven years, 38% were undergoing psychotherapeutic treatment [25].

¹⁷ Values had been rounded in the publication.

Core theme from the perspective of staff. The implementation of FIT64b had complex impacts on the treatment culture and on staff, as illustrated in the theme "impact on staff, treatment culture, and ethos" [25]. This theme includes the following subcategories: "relief through increased freedom in therapeutic decisions", "less bureaucracy and organizational effort", "closer relationships and better understanding of service users", "change in therapeutic attitude", and "greater job satisfaction" [25]. Further details regarding the relevance of this core theme can be found in the sections 4.1 and 4.3.

Results for study 3 – Indefrey S, Braun B, von Peter S, Bechdolf A, Birker T, Duve A, Hardt O, Heiser P, Hojes K, Rehr B, Scherk H, Schulz-Du Bois AC, Wilms B, Heinze M. Implementation of a global treatment budget in psychiatric departments in Germany – results and critical factors for success from the staff perspective. Front. Psychiatry, 2020; 11:610.

<u>Sample characteristics.</u> The sample size was N = 695, consisting of 127 physicians, 84 psychologists, and 352 nurses. The mean response rates by department ranged between 31-88% for physicians/psychologists and 14-87% for nurses [24]. The majority of participants were female (73%), had a mean age of 41 years and had, on average, 12 years of work experience in psychiatry. 62% had worked full time in general psychiatry (40%). Physicians (75%) and psychologists (61%) mainly worked in an outpatient treatment setting, while nurses (77%) mainly worked in an inpatient treatment setting [24].

Experiences (EX) and evaluations (EV) of FIT64b-SCs. Cronbach's α for the developed questionnaire "Characteristics, Structures and Procedures of Model Projects" was good (> 0.8) for physicians'/psychologists' and nurses' questions, according to the definition by Cronbach [67]. With respect to eight of the ten FIT64b-SCs, nurses' EX indicated a lesser grade of experience/information for nurses with FIT64b-SCs. For nurses, no significant relation between EX and project duration was found ($x^2(2) = 3.323$, p = 0.190, n = 304), while the Chi-square test was significant for physicians/psychologists (2) = 9.948, p = 0.007, Cramer's V = 0.235, n = 180) [24, 68].

Up to 31% of physicians/psychologists and 35% of nurses were not experienced with at least one of the FIT64b-SCs. Physicians/psychologists were least experienced with the FIT64b-SC "outreach home care" (31%), while nurses were least experienced with the component "expansion of professional expertise" (35%) [24]. Both groups were most experienced with the FIT64b-SC "multiprofessional cooperation" (2% lack of experience for physicians/psychologists, 4% for nurses) [24]. The largest difference in experiences between physicians/psychologists and nurses related to the specific component "expansion of professional expertise" (20% of physicians/psychologists versus 35% of nurses stated "nonexistent"), the lowest to "sovereign steering of services" (8% of both groups stated "nonexistent") [24].

The mean value for EV was 4.4 of a maximum of 5 points for physicians/psychologists and 3.9 for nurses. This indicates rather positive evaluations of FIT64b by the nurses surveyed and even more positive evaluations by physicians/psychologists [24]. The highest mean values of EV were found for the component "sovereign steering of services" (4.6 for physicians/psychologists, 4.2 for nurses), the lowest for the component "cooperation across sectors" (4.0 points for physicians/psychologists, 3.6 for nurses). The EV of the occupational groups differed most for the components "outreach home care" and "multiprofessional cooperation" (both with a difference of 0.6), while it differed least for the component "shifting in- to outpatient setting" (difference of 0.3) [24].

Critical factors for successful FIT64b implementation. The regression model was significant for physicians/psychologists for EV ($\chi^2(6) = 24.477$, p < 0.001, n = 68), as well as the nurses' model for EV ($\chi^2(4) = 32.605$, p < 0.001, n = 112) [24]. The chance of a positive evaluation of FIT64b-SCs (EV) for physicians/psychologists increased 16.5-fold when the "opportunity to join training programs on the objectives of FIT64b" was positively rated (p = 0.008), 13.2-fold for a higher "number of nurses/special therapists per physician/psychologist" (> versus < median 3.3) (p = 0.013), and 10.4fold for a "project duration" exceeding two years (versus < two years) (p = 0.036). The inclusion of the coefficients "age", "sum of positively rated work conditions" (> versus < 50% positively rated), and "duration of employment in psychiatry" did not contribute significantly to the prediction of the EV outcome. 49% of the variance of EV could be explained by the three significant independent variables, corresponding to a strong effect, according to the definition by Cohen [24, 68]. For nurses, the chance of a positive FIT64b-SCs evaluation (EV) increased 5.1-fold for a higher "sum of positively rated work conditions" (> versus < 50% positively rated) (p = 0.001), and 4.9-fold for the "opportunity to join training programs on the objectives of FIT64b" (p < 0.001). The inclusion of the coefficients "supervisor for other nurses" and "project duration" (> versus < 2 years) did not contribute significantly to the prediction of the EV outcome. 34% of the variance of EV could be explained by the three significant independent variables, corresponding to a strong effect, according to the definition by Cohen [24, 68].

4. Discussion

In the following, the synthesis of the results (4.1), limitations of the thesis (4.2), and future directions (4.3), derived from the results, are presented.

4.1 Synthesis of the results

This thesis aims to study experiences, evaluations, and critical factors for successful FIT64b implementation from the staff perspective. The four research questions for studying this aim shall be answered in the following.

(1) Might project overarching FIT64b-SCs describe structural and procedural changes that follow FIT64b implementation from a staff perspective?

Eleven empirically and theoretically grounded FIT64b-SCs were defined and operationalized during a multi-step process [32]. They integrate structural and procedural variations of FIT64b projects, making them comparable to each other and suitable to be assessed for research [2, 32, 54]. On a practical level, the knowledge of FIT64b-SCs may guide the application, monitoring, and quality assurance of FIT64b projects [32, 54]. On a theoretical level, the components may systematically guide FIT64b project development and implementation. Against the background of well-known issues of Mixed Methods approaches, the components were of a high methodological value for the development of research instruments and for analyzing and integrating the results from the qualitative and the quantitative study of this thesis [54, 69, 70]. The components and their operationalization were further evaluated during the "EvaMod64b" study: face and content validity, as well as internal consistency were tested [54]. They already served as a theoretical basis for the development of a sum score, quantifying differences between FIT64b departments [2, 54], the "Scale for Evaluation of Psychiatric Integrative and Continuous Care" (SEPICC) [71], and the qualitative analysis of common change mechanisms for FIT64b projects [25]. In intermediate results for the multi-center, prospective controlled cohort study "PsychCare" (see section 4.3), the components proved valid for capturing structural and procedural variations of FIT64b projects from the perspective of staff [73]. In the "PsychCare" study, the specific components were also supplemented by specific components from the perspective of service users by utilizing a co-productive research methodology [72, 73].

(2) How are FIT64b-SCs experienced and evaluated by staff?

Experiences with FIT64b were mainly positively evaluated by staff in the qualitative study 2 and at least rather positively in the quantitative study 3 (physicians'/psychologists' EV 4.4 out of 5 points, nurses EV 3.9 out of 5) [24, 25]. The proportion of staff who reported having had no experience with at least one FIT64b-SC (up to 35% of staff) may indicate that not all components, such as "outreach home care" and "expansion of professional expertise", were fully implemented, or that staff were not fully informed about the new treatment elements at the time of data collection.

Both groups were most experienced with the FIT64b-SC "multiprofessional cooperation". While this shows a high significance of the component for the FIT64b daily work routine, the evaluations of the occupational groups differed widely for this component (0.6 out of 5 points), as described below [24]. The finding of component "cooperation across sectors" being the least well-evaluated by staff matches other research, indicating that cross-sectoral care is rare in FIT64b. This implies that a central aim of the § 64b SGB V is currently not being reached nationwide [14, 24, 38]. Implications of these findings can be found in section 4.3.

In both the studies 2 and 3, an attitude change following the implementation of FIT64b was found [24, 25]. This illustrates impacts of structural and organizational changes on the treatment culture and on staff attitudes [25]. Staff identified themselves most strongly with the FIT64b-SC "sovereign steering of services" [24]. A greater therapeutic freedom in terms of broader and more flexible opportunities to combine therapeutic options and to take more sovereign decisions about the course of treatment (e.g. independent of the Medical Service of Health Funds (MDK) and independent from a specific treatment setting) was described positively in study 2 [25] and rated positively in study 3 [24]. While this aspect was regarded as allowing to adapt treatment more strongly to the needs of service users, this greater therapeutic freedom was simultaneously described by some staff as "rendering daily routines more complex" [2:7] and "stressful freedom" [25:10]. Studies 2 and 3 also documented an attitude change in staff towards a stronger involvement of informal caregivers such as an understanding of the role of informal caregivers as active partners from the early stages of the treatment process, instead of only being considered a mere source of information [24, 25]. Study 2 further illustrated impacts of the FIT64b implementation on therapeutic relationships. These relationships were described as allowing for long-term interactions under FIT64b conditions, leading to a closer relationship, deeper understanding, and a more confident and autonomy-promoting attitude of staff towards service users such as by the higher continuity of treatment across different settings [25]. Staff further described an increased reliance on service users' competencies and resources, driven by the described therapeutic freedom and the stronger therapeutic relationship [25].

Discordant results between the qualitative and the quantitative study emerged for the aspects of bureaucracy/organizational effort, job satisfaction, and expansion of professional expertise. The development of bureaucracy and organizational effort seems to be heterogeneously experienced over the participating FIT64b departments [2, 24, 25]. A reason for this may be the scope of the contract with health insurance companies for departments which are under contract to only some health insurance companies, and therefore may have to manage double routines [2]. Another reason for these discrepant experiences may be differences in the degree of implementation. For example, some FIT64b departments had implemented new forms of outpatient and outreach services, while others did not [2, 34]. This may also possibly influence the amount of experienced bureaucracy and organizational effort, such as by the need for additional implementation-related activities as concept development, team building, or the organization of home visits. While described positively by staff [25], job satisfaction was not measured in the quantitative study of the thesis [24]. It remains unclear whether different experiences and evaluations between the occupational groups may also relate to different job satisfaction following FIT64b implementation. Possible reasons for differences between experiences and evaluations for the FIT64b-SC "expansion of professional expertise" are described below.

(3) What are the critical factors for the successful FIT64b implementation from the staff perspective?

The opportunity to join training programs on the objectives of FIT64b was the only factor for successful FIT64b implementation shared by physicians, psychologists, and nurses [24]. For physicians/psychologists, this aspect was the most important factor for success. For nurses, it was the second (following work conditions). Given the importance for staff, a remarkable 36% of physicians/psychologists and 27% of nurses stated that no training programs on the objectives of FIT64b existed in their department [24]. For physicians/psychologists, the second most important factor for success was a higher number of nurses/special therapists per physician/psychologist, possibly relieving some organizational or other burden placed on physicians/psychologists during the FIT64b implementation [2, 24]. Project duration was the third most important factor for successful implementation from the perspective of physicians/psychologists [24]. This may indicate that time is needed for staff to grow accustomed to changes following the implementation of FIT64b, undergoing certain modifications of professional attitudes and work procedures [2, 24, 81]. From the perspective of nurses, work conditions were the most important factor for successful FIT64b implementation [24]. The found importance of work conditions from the perspective of nurses matches other research, illustrating the importance of work conditions on

outcomes for nurses (e.g. lower rates of burnout), as well as on outcomes for service users and departments (e.g. lower rates of adverse clinical events [24, 78, 82-84]. The factors for successful implementation together explained 49% of the variance of physicians'/psychologists' and 34% of nurses' evaluations [24]. The results illustrate the different needs of the occupational groups regarding the implementation process, as will be discussed in the section 4.3.

(4) Are there differences between the occupational groups regarding experiences and evaluations?

As shown by study 3, nurses were both less experienced with FIT64b-SCs and their evaluations were lower than those of physicians/psychologists in every FIT64b-SC [2, 24]. This may indicate that physicians/psychologists more easily assimilate FIT64b-related changes than nurses - even after a two year project duration [24]. A reason for these differences may be found in the critical factors for successful FIT64b implementation. While these factors differed between the groups, results for both the groups indicate the significance of structural aspects of FIT64b departments and characteristics of FIT64b for the explanation of the variance of staff evaluations [24]. Structural aspects of FIT64b departments (the sum of positively rated work conditions, the number of nurses/special therapists per physician/psychologist) and characteristics of FIT64b (project duration, the opportunity to join training programs on the objectives of FIT64b) were found to be important to explain variance of staff evaluations, while characteristics of staff (e.g. age, gender, qualification) were not found to be critical factors for successful FIT64b implementation [24].

The evaluations of the occupational groups differed most for the FIT64b-SCs "outreach home care" and "multiprofessional cooperation", both being more positively evaluated (+ 0.6 out of 5 points) by physicians/psychologists [24]. A reason for the differences between the occupational groups for the former may be that physicians/psychologists who are possibly more involved in theoretical developments than nurses may thus have a greater opportunity of identifying with FIT64b-SCs which may lead to greater experience and higher evaluations [2, 24, 74]. Although the FIT64b-SC "multiprofessional cooperation" was most strongly experienced by staff, the high discrepancy in its evaluation may indicate divergent and possibly colliding viewpoints for occupational groups, which could present a barrier for FIT64b implementation [24]. Different and colliding professional attitudes between the occupational groups in psychiatry/psychotherapy are a commonly observed phenomenon, indicating that interprofessional cooperation is not necessarily supported by all occupational groups and even that territorial behavior may occur, meaning that occupational groups may implicitly and/or explicitly defend their professional roles against each other [78-80].

Unlike study 2, reporting an increased expansion of professional expertise for nurses [25], experiences differed mostly between the groups for this FIT64b-SC in study 3 [24]. Along with possible methodological limitations (4.2), a reason for this finding may be that professional profiles for nurses may not have changed comparably to those of physicians/psychologists, such as being due to an unbalanced (re)distribution of tasks between the occupational groups during the implementation process [24]. While this aspect was not captured in the qualitative study of the thesis, it was found in a not standardized intervention study with pre-post comparison by Bartholomeyczik et al. (2008). The authors reported that physicians passed on tasks to nurses during the (in this study reported) implementation process, while nurses were unable to reciprocate or engage other occupational groups [24, 75]. Moreover, the differences regarding the expansion of professional expertise may be an indicator of "role blurring" [76].

For FIT64b, overlapping competencies may occur, leading to confusion about role definitions and its practice boundaries for occupational groups. While some staff may feel that they 'do everything', others may feel underutilized because of role blurring [77:192]. Implications of these findings for future FIT64b implementation may be found in the section 4.3.

4.2 Limitations

In this thesis, a Mixed Methods exploratory and cross-sectional approach was used to study experiences, evaluations, and critical factors for successful FIT64b implementation from the perspective of physicians, psychologists, and nurses of twelve FIT64b departments. FIT64b departments were surveyed without matching to control departments and/or control service users from standard care. This study design does not allow for the drawing of conclusions about causal inferences and the generalizability of the results. In the qualitative studies 1 and 2, focus groups were mostly conducted with staff, service users, and informal caregivers as a mixed The intention of this multi-stakeholder approach was to gain multi-faceted insights into experiences and evaluations of FIT64b implementation, to enable controversial discussion between the participants, and to explore as much as possible thematic fields about FIT64b implementation. However, further focus groups with staff, focusing on staff-specific themes, might have deepened the understanding of the implementation mechanisms from the staff perspective, such as the expansion of professional expertise, interprofessional cooperation, and possible conflicting viewpoints between the occupational groups.

The response rates by department differed widely, and the exploratory findings were (regarding that response rates were as low as 14% in some of the cases) therefore prone to selection bias. Furthermore, a self-reporting approach is vulnerable to information bias [85]. Staff might have refused to participate in the study because they did not identify with the aims and implications of FIT64b. Those staff might have given more negative answers, felt pressured to participate, or even feared negative consequences despite the guaranteed anonymity, especially in focus groups that included participants from different hierarchical levels [24]. On the other hand, staff who supported the implementation might also have been overrepresented [24]. Although the findings of this thesis were the first staff-related findings from German FIT64b projects and the explained variance of staff evaluations, in terms of factors for successful implementation, correspond to a strong effect, other relevant factors remain to be identified [24], as described in section 4.3

4.3 Future directions

Based on the results of the three studies of the thesis, several future directions can be drawn. For reasons of space, only main aspects are discussed in the following.

Understanding FIT64b as an interprofessional¹⁹ project

This thesis revealed considerable differences in the experiences and evaluations of the FIT64b-SCs "expansion of professional expertise" and "multiprofessional cooperation" between physicians/psychologists and nurses [24]. These findings point to divergent and possibly conflicting viewpoints between these groups, and indicate different needs for guiding the implementation process. As suggested by other research, these differences may express various individual, professional, organizational, and structural aspects that may influence interprofessional cooperation, such as the lack of a common communicative approach [86], and are known to cause strained relations between occupational groups and increase the possibility of errors in clinical practice [87-89].

For psychiatry/psychotherapy, as areas with high demands on interprofessionality, it is important to address the found different and possibly contradictory needs, and to consider FIT64b as an interprofessional project. Person-centered and need-adapted treatment requires interprofessional cooperation to enable treatment for the service user as a person with different facets to be met by different occupational groups [15, 90]. This may require the deeper integration of tasks and equal participation opportunities for all the occupational groups, e.g. by implementing new forms of cooperation and training programs [2, 24, 79]. For example, enhancing the competencies of occupational groups for different perceptions and approaches to cooperation may foster mutual understanding and an effective interprofessional relationship. This could be the matching of needs, tasks, and goals, according to defined and shared interprofessional objectives of treatment and the development of a common professional language, as well as common practices and standards related to a certain condition [13, 16, 19, 24, 79]. These aspects are in line with current issues for medical professionals' education [91, 92].

According to the recommendations of the German "Advisory Council on the Assessment of Developments in the Health Care System" (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen), tasks for occupational groups should be derived from demographic, structural, and innovation-related requirements of the healthcare system instead of focusing on the single interests of individual occupational groups [9, 19, 24]. For example, prevention, health promotion, and different

¹⁹ The term "interprofessionality" is used in this thesis to express the understanding of FIT64b, requiring a high degree of cooperation between occupational groups. The term indicates the need to unite the different perspectives of occupational groups by targeted interventions, aiming to go beyond the parallel existence of occupational groups [111].

forms of outreach care are fields with high social significance which are a constitutive part of nursing [93, 94]. This fields may thus have a high potential to expand the professional expertise in psychiatric nursing. Therefore, to answer the question about innovative ways of interprofessional cooperation, as the definition of professional profiles for occupational groups, may be a very interesting theme for further FIT64b development. For FIT64b, aiming to foster cross-sectoral treatment, besides cooperation on an intraorganizational level, cooperation on an interorganizational and/or intersectoral level is also required for offering person-centered and need-adapted treatment [90, 95]. It seems thus important to anchor the claim for interprofessional cooperation structurally and organizationally by implementing interventions fostering interprofessional cooperation on various levels [16, 96].

Organizational development to facilitate the implementation of FIT64b

In this thesis, structural aspects of FIT64b departments (the sum of positively rated work conditions, the number of nurses/special therapists per physician/psychologist) and characteristics of FIT64b (project duration, the opportunity to join training programs on the objectives of FIT64b) were found to be important to explain variance of staff evaluations, while individual characteristics of staff (e.g. age, gender, qualification) were not found to be critical factors for successful FIT64b implementation [24]. Three implications may be derived from this.

First, this finding indicates that successful FIT64b implementation depends on the development of structures and organizational behavior, such as the personnel assessment and the design of work conditions [24]. This matches other research findings, showing the importance of structures and organizational behavior for different outcome parameters for staff, service users, and psychiatric departments [82, 97-99]. Positive aspects of organizational behavior, such as leadership skills, strong collegial nurse-physician relationships, and higher nurse to service user staffing ratios have been associated with the reduced occurrence of nurse burnout, as well as lower rates of adverse clinical events, such as staff injuries and various forms of conflict [78, 83, 84, 100]. In a study of Germany, the risk of implicit rationing for physicians/psychologists was found to increase with the occurrence of a highly-perceived proportion of administrative work, an inadequately-perceived medical/psychological staffing for a good medical/psychological therapy, negatively evaluated relationships with superiors/position in hierarchy, and a higher amount of service users [98]. Besides the area of attention/conversation with service users (stated by 59% of physicians/psychologists/ 60% of nurses), several other treatment areas were reported to have been affected by implicit rationing, such group activities with service users, communication with informal caregivers, intra/ interorganizational cooperation, coordination, and documentation [98].

This illustrates the importance of the structures and organizational behavior for FIT64b implementation, and indicates that staffing and other work conditions may not be viewed separately from each other [82, 98, 99].

Second, the above finding points to the importance of implementing obligatory training programs on the objectives of FIT64b. This aspect emerged as the only factor for successful implementation from the perspective of both groups [24]. The discrepancy between its importance from the staff perspective and its implementation at the time of data collection (as described in section 4.1) indicates a high possible return on investment for the implementation of training programs [24]. This conclusion matches findings from workplace research finding communication of an innovation, its benefits, and the need for innovation as "the most important factor" for successful implementation [101:285,102]. The effective communication of an innovation as FIT64b requires the involvement of staff affected by it, and should address possible fears and prejudices [101]. Training programs may increase staff experiences with FIT64b, which is an essential factor for attaining a better understanding of and identification with FIT64b-SCs, as described in section 1.4. Third, the relevance of FIT64b characteristics and structural aspects indicates that FIT64b implementation may be facilitated by different systematic internal (e.g. quality management) and/or external support opportunities (e.g. systematic change management) [24]. Such offers may systematically promote the modification of structures, organizational behavior, and attitudes towards FIT64b [24]. The relevance of project duration as a critical factor for successful FIT64b implementation and the finding of the relevance of preexisting FIT64b-like structures (such as the RPB) for the degree of implementation of current FIT64b projects illustrate a processual character of the FIT64b implementation [1]. For both, individual staff members and FIT64b departments, it takes time to assimilate to new forms of work, especially in the departure phase during the first two years of FIT64b implementation, where double routines, the risk of an increased workload, and other restraining forces have to be managed [2, 24]. Familiar routines have to be modified or completely changed, new treatment concepts to be implemented, competencies and tasks to be developed which may lead to conflicts like role blurring and territorial behavior [76, 77, 80]. New forms of work and interprofessional cooperation may be difficult to implement for people systemically involved in departments' structures and procedures. Therefore, systematic internal and/or external support opportunities may help to prevent the rejection of FIT64b, inner emigration of staff, overload, and interprofessional conflicts as overlapping and unclear competencies [24, 77, 80].

Fostering cross-sectoral treatment

In current practice, the scope of FIT64b supply is defined differently, whether including complementary psychiatric supply services or not [34, 37]. Office-based psychiatrists and psychologists are not integrated in the GTB, and not all FIT64b include service users from all health insurance companies [2, 37]. The latter case means that not all service users receive treatment according to § 64b SGB V, and double routines of FIT64b treatment and standard care have to be installed [2]. Along with this, the lack of staff experiences and poor evaluations of the FIT64b-SC "cooperation across sectors" found by this thesis indicate that this FIT64b-SC is in need of improved implementation. This result matches other research findings, suggesting that the fragmentation of the German mental health care system is only partially addressed by the current FIT64b implementation practice, as long as the application of the GTB is limited to the hospital sector [14, 25, 38, 54]. For example, the current FIT64b projects entail services according to SGB V, but not for participation, according to SGB IX and XII [14]. For FIT64b, the issue remains to be solved how services, financed by different German Social Code Books, may be combined [14, 38, 103, 104]. As a step towards interorganizational cooperation and the integration of treatment and care, aiming to link treatment establishment services from different Social Code Books, the of a community mental health center has been discussed and has already singularly been established [38, 105]. The concept of this center is based on the "Functional Basic Model for the psychiatric care of people with severe mental illness" [14]. At the center of this model is a coordination and counseling center combining mobile treatment and prevention with mobile psychosocial support, such as planning rehabilitation and participation opportunities [14]. Besides support in psychosocial crisis situations, supplier-neutral counseling and coordination for health-related (SGB V) and integration assistance (SGB XII) are offered, which allow for the need-adapted supply of service users with complex multiple needs from one source [105].

Though this model project offers one possibility for enhancing low-threshold and need-adapted accessibility of services, the problem of fragmentation remains at the macro level of the German mental health care system. Incentives for a broader application of cross-sectoral treatment (such as by enabling the combination of services from different German Social Code Books) are needed to improve this state of affairs for FIT64b and the German mental health care system in general.

Further research

In this thesis, structural and organizational changes following FIT64b implementation were found to impact staff, treatment culture, and ethos – aspects which were not captured by previous FIT64b or RPB studies [24, 25]. While the staff perspective was a blind spot in research on FIT64b, the thesis illustrates the importance of staff involvement and to gain an understanding of staff experiences and evaluations to facilitate successful implementation processes in personal services. The staff perspective should therefore be focused on in future FIT64b research and implementation efforts. As the study design of this thesis was cross-sectional and explorative in nature, the findings need further substantiation to guide the theoretical and practical development of FIT64b implementation. Prospective and longitudinal studies are needed that directly link staff attitudes to structural, organizational, and individual staff variables. Such studies may ascertain whether the results are a necessary consequence of FIT64b implementation and enable the drawing of conclusions about the generalizability of the results. To enable the transferability of further research findings, the integration of further occupational groups, such as special therapists, is important. Differentiating between physicians' and psychologists' assessments might enable further knowledge upon occupation-related differences in FIT64b implementation. As the aspects of bureaucracy/organizational effort, job satisfaction, and the development of expansion of professional expertise (e.g. (re)distribution of tasks) following the implementation of FIT64b remain unclear, these may also be questions for further research. As work conditions were analyzed as a whole, further research should analyze subcategories of this construct, such as supervision and the presence of hierarchy, interprofessional cooperation, personnel assessment, or the participatory opportunities for different occupational groups and their relation to FIT64b implementation. For example, this may help to understand the relevance of personnel assessment, as one factor for successful FIT64b implementation found by this thesis, in relation to other work conditions. It would further be interesting to survey the relevance of other individual characteristics of staff, such as personal traits, as the individual characteristics of staff analyzed in this thesis explained no variance of staff evaluations. An interesting hypothesis may be whether viable staff attitudes are more important than stable individual characteristics in explaining variations in staff evaluations. Employing a multilevel analysis or structural equation modelling approach might be useful for understanding variables arising from different organizational levels and their possible interplay for explaining staff evaluations [24]. Further qualitative research on FIT64b might focus more strongly on the understanding of differences between the occupational groups.

Research on FIT64b may be facilitated by combining subjective (e.g. experiences, evaluations) and objective parameters (e.g. amount of staff, quantity of overtime, amount of further and continuing education, sick days). An example of this strategy is the "PsychCare" study, which combines the study designs of the studies "Eva64" and "EvaMod64b" [106]. The aim of this multi-center, prospective-controlled cohort study is to evaluate the effects of FIT64b (benefit, costs, and efficiency) based on a controlled part (under inclusion of routine data of ten FIT64b and ten control departments), as well as integrating quantitative primary and secondary data and the qualitative experiences of service users, informal caregivers, and staff. Data collection has taken place since February 2018, and results are expected from the end of the year 2020

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6. Annex

Eidesstattliche Versicherung und ausführliche Anteilserklärung

Eidesstattliche Versicherung

"Ich, Sonja Claire Indefrey, versichere an Eides statt durch meine eigenhändige Unterschrift,

dass ich die vorgelegte Dissertation mit dem Thema: "Evaluation of flexible and integrative

psychiatric treatment according to § 64b SGB V in Germany - A Mixed Methods staff-oriented

exploratory study" selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine

anderen als die angegebenen Quellen und Hilfsmittel genutzt habe.

Alle Stellen, die wörtlich oder dem Sinne nach auf Publikationen oder Vorträgen anderer

Autoren beruhen, sind als solche in korrekter Zitierung kenntlich gemacht. Die Abschnitte zu

Methodik (insbesondere praktische Arbeiten, Laborbestimmungen, statistische Aufarbeitung)

und Resultaten (insbesondere Abbildungen, Graphiken und Tabellen) werden von mir

verantwortet.

Meine Anteile an etwaigen Publikationen zu dieser Dissertation entsprechen denen, die in der

untenstehenden gemeinsamen Erklärung mit dem Betreuer, angegeben sind. Für sämtliche im

Rahmen der Dissertation entstandenen Publikationen wurden die Richtlinien des ICMJE

(International Committee of Medical Journal Editors; www.icmje.og) zur Autorenschaft

eingehalten. Ich erkläre ferner, dass mir die Satzung der Charité – Universitätsmedizin Berlin

zur Sicherung Guter Wissenschaftlicher Praxis bekannt ist und ich mich zur Einhaltung dieser

Satzung verpflichte.

Die Bedeutung dieser eidesstattlichen Versicherung und die strafrechtlichen Folgen einer

unwahren eidesstattlichen Versicherung (§§ 156, 161 des Strafgesetzbuches) sind mir bekannt

und bewusst."

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Datum	Unterschrift	

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Anteilserklärung an den erfolgten Publikationen

Sonja Indefrey hatte folgenden Anteil an den folgenden Publikationen:

<u>Publikation 1:</u> von Peter S, Ignatyev Y, Indefrey S, Johne J, Schwarz J, Timm J, Heinze M. Spezifische Merkmale zur Einstufung der Modellversorgung nach §64b SGB V. Nervenarzt, 2018; 89(5):559-564. DOI: 10.1007/s00115-017-0459-z.

Beitrag im Einzelnen: Parallel zur Erhebung und im Sinne der Grounded Theory Methodologie hat Sonja Indefrey die spezifischen Merkmale zur Einstufung der Modellversorgung und ihre Operationalisierungen gemeinsam mit Prof. Dr. Sebastian von Peter und den anderen Co-Autoren im Rahmen einer Forschungswerkstatt fortlaufend überarbeitet und angepasst. Sonja Indefrey war außerdem unter der Supervision von Dr. Yuriy Ignatyev für die Erhebung, Verwaltung und Auswertung der verwendeten Strukturdaten zuständig, woraus sich die Tabelle 1 der Publikation speist. Sie war an der Überarbeitung des Artikels während des Review-Verfahrens beteiligt.

<u>Publikation 2:</u> Schwarz J, Galbusera L, Bechdolf A, Birker T, Deister A, Duve A, Heiser P, Hojes K, Indefrey S, Johne J, Rehr B, Rout S, Scherk H, Schulz-Du Bois A, Wilms B, Zedlick D, Zeipert M, Heinze M, von Peter S. Changes in German Mental Health Care by Implementing a Global Treatment Budget – A Mixed-Method Process Evaluation Study. Front. Psychiatry, 2020; 11:426. DOI: 10.3389/fpsyt.2020.00426.

Beitrag im Einzelnen: Sonja Indefrey war an (A) der Vorbereitung der Einzelinterviews und Fokusgruppen, (B) der Datenerhebung, (C) der Datenanalyse und (D) der Qualitätssicherung der Studienergebnisse wesentlich beteiligt. (A) umfasste die Mitarbeit bei der Entwicklung der Rekrutierungsstrategie und die Entwicklung des Interviewleitfadens. (B) umfasste die Durchführung von Fokusgruppen, gemeinsam mit Prof. Dr. Sebastian von Peter, sowie die selbstständige Durchführung von Einzelinterviews. (C) umfasste die qualitative Auswertung von Mitarbeiter- und der Patientenbezogenen Daten nach Mayring. Hieraus entstanden für die Publikation verwendete Kategorienbäume mit Haupt-/Nebenkategorien und Ankerbeispielen. (D) umfasste die fortlaufende Ergebnisvalidierung innerhalb der Forschungsgruppe (Forschungswerkstatt) sowie die Aufbereitung der Ergebnisse zur Präsentation und Diskussion im Rahmen der Steuerungsgruppe mit den kooperierenden Kliniken.

Publikation 3: Indefrey S, Braun B, von Peter S, Bechdolf A, Birker T, Duve A, Hardt O, Heiser P, Hojes K, Rehr B, Scherk H, Schulz-Du Bois AC, Wilms B, Heinze M. Implementation of a Global Treatment Budget in Psychiatric Departments in Germany—Results and Critical Factors for Success From the Staff Perspective. Front. Psychiatry, 2020; 11:610. DOI: 10.3389/fpsyt.2020.00610.

Beitrag im Einzelnen: Sonja Indefrey entwickelte mit Dr. Bernard Braun das Studiendesign. Sie war für die Entwicklung einer standardisierten schriftlichen Zusatzbefragung der Kliniken zu Merkmalen der Implementierung der Modellprojekte, der Datenerhebung und der Datenverwaltung zuständig. Die statistischen Analysen wurden von Sonja Indefrey und Dr. Bernard Braun, als Mitglieder zweier unterschiedlicher Institutionen, parallel und unabhängig voneinander durchgeführt. Die Interpretation der Daten und deren Diskussion vor dem Hintergrund einer internationalen Literaturrecherche wurden von Sonja Indefrey selbstständig durchgeführt. Sie verfasste das gesamte Manuskript inklusive der Entwicklung der Fragestellungen, erstellte alle Tabellen und alle Abbildungen sowie das ergänzende Material selbstständig und war für die gesamte Überarbeitung des Manuskripts im Rahmen des Reviewprozesses verantwortlich. Sie war für die Kommunikation mit den Kliniken und Co-Autoren sowie die Aufbereitung und gemeinsame Diskussion der Ergebnisse im Rahmen der Steuerungsgruppe verantwortlich.

Unterschrift der Doktorandin

Druckexemplare der ausgewählten Publikationen

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Changes in German Mental Health Care by Implementing a Global Treatment Budget—A Mixed-Method Process Evaluation Study

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Background: Internationally, there is a broad spectrum of outreach and integrative care models, whereas in Germany acute psychiatric treatment is still mostly provided in inpatient settings. To overcome this, a new legal framework (§64b Social Code V) has been introduced, promoting "Flexible and Integrative Treatment" Models (FIT64b), based on a "Global Treatment Budget" (GTB) financing approach. 23 hospitals have implemented the framework according to local needs and concepts. Prior research has already identified specific components of FIT64b. Based on this, our paper aims to examine the implementation process and underpinning change mechanisms of GTB-based FIT64b models from a staff, service user and caregiver perspective.

Method: 31 focus groups and 15 semi-structured interviews were conducted with hospital staff (n = 138), service users (n = 63), and caregivers (n = 35) in 10 psychiatric hospitals implementing FIT64b. Using qualitative analysis, we identified 5 core themes describing the implementation process, which were theoretically modeled into a logical diagram. The core mechanisms of change were thus identified across themes. Additional structural and semi-quantitative performance data was collected from all study departments.

Results: The qualitative analysis showed that the shift from a daily- and performance-based payment to a lump-sum GTB and the shift of resources from in- to outpatient settings were of crucial importance for the process of change. Saved budget shares could be reinvested to integrate in-, out-, and day-patient units and to set up outreach home care. Clinicians reported feeling relieved by the increase of treatment options. They also emphasized a stronger relationship with and a better understanding of service users and a simplification of bureaucracy. Finally, service users and caregivers experienced higher need-adaptedness of treatment, a feeling of deeper understanding and safety, and the possibility to maintain everyday life during treatment. Finally, two FIT64b implementation prototypes were classified according to the semi-quantitative performance data.

Conclusion: Based on the results, we developed 3 core mechanisms of change of FIT64b models: (1) Need-adaptedness and flexibility; (2) Continuity of care; (3) Maintaining everyday life. Our findings outline and emphasize the potential a GTB approach may have for improving psychiatric hospital services.

Keywords: global budget, capitation, block grant, integrated care, cross-sectoral mental health care, process evaluation, mixed method, complex intervention

INTRODUCTION

Internationally, there is a broad spectrum of team-based outreach and integrative psychiatric care models dedicated to acute treatment (1-3). Yet, intensive psychiatric care in Germany is almost exclusively provided in inpatient hospital settings (4). To improve this situation, in 2013 a new legislation (\$64b Social Code V) has been introduced to promote "Flexible and Integrative Treatment" Models (FIT64b). Importantly, FIT64b is a legal framework and no concrete model of care, leading to an implementation according to providers' specific context, needs and concepts. Nevertheless, all FIT64b models are based on a Global Treatment Budget (GTB), which is an annual lump-sum budget applied across all hospital settings (5). The GTB is negotiated between care providers and health insurances on the basis of historical expenditure and of the number of patients treated. Thus, this financing approach can be described as a middle ground between block contracts (in which providers are payed a fixed amount to deliver a specific, usually broadly-defined, service) and capitation (in which providers receive lump-sum payments based on the number of patients treated) (6, 7).

Evidence has shown that daily- and performance-based remuneration, which is the predominant financing approach for German psychiatric inpatient care, leads to treat service users (SU) as cost-intensively as possible, i.e., mainly in inpatient settings. This in turn also contributes to the fragmentation of meantal health care services, thus increasing the inpatient-outpatient gap (8). A GTB approach contrasts this tendency toward fragmentation by providing hospitals with the financial

Abbreviations: ACT, Assertive Community Treatment; CoC, Continuity of Care; CRT, Crisis Resolution Team; EvaMod64b, Evaluation of Models according to §64b of Social Code V; FIT64b, Flexible and Integrated Treatment according to §64b of Social Code V; HIS, Hospital Information System; MRC, UK Medical Research Council; PREMs, Patient Reported Experience Measures; SU, Service User

security and flexibility needed to develop more integrative, ambulatory and outreach psychiatric care (9). However, GTBs only partially address the problem of fragmentation as long as they are limited to the hospital sector.

To date, 23 German psychiatric hospitals have introduced FIT64b models based on a GTB. The first outcome evaluations of these models have already shown positive effects, such as a reduction in inpatient length of stay, as well as an increase in the number of patients treated in outpatient and outreach settings (10–14). Most importantly, clinical outcomes (e.g., HoNOS, CGI, GAF) improved and overall psychiatric care costs were kept stable or even decreased (10, 15–18).

Although such outcome studies have shown that the introduction of GTB may yield notable changes in conventional (i.e., inpatient) services, it is still not clear how such changes might be brought about. Previous research, evaluating the process of FIT64b models, has identified 11 specific program components, which were operationalized and validated (12, 14, 19). In addition to these first attempts at operationally defining FIT64b models, further research is required to understand how these overarching components are implemented and how their interaction may produce change. Therefore, the following research questions will be adressed:

- 1. How do FIT64b models work and what are their common mechanisms of impact?
- 2. How do these impact mechanisms vary depending on different FIT64b implementations?
- 3. What role does the financing approach play in the implementation of FIT64b models?

The exploration of this research questions is especially necessary in order to delineate the multivariate effects of these treatment models on clinical practices and on the experiences of SU and carers.

The UK Medical Research Council (MRC) guidance on evaluating complex interventions recommends modeling, both theoretically and empirically, how the intervention processes are associated with changes in outcome (20). Following this guidance, in this paper we aim to explore the nexus between structure, process and outcome in FIT64b models. Accordingly, we develop a logical diagram that unpacks the underpinning mechanisms of change, starting from the resources and inputs up to the impacts on the different stakeholders involved.

METHODS

Design

The present study is part of the EvaMod64b Project, a multicentre study aimed at exploring the experiences and evaluations of FIT64b models from three stakeholders' perspectives (hospital staff, SU, carers). Using a Mixed-Methods approach, the EvaMod64b Project combined a standardized survey, routine hospital data, and a semi-quantitative and qualitative assessment (11–14, 19, 21). An overview of quantitative outcomes and of some preliminary qualitative findings has been reported in a first publication on this project (12). To deepen the understanding of the overarching impact mechanisms of FIT64b models and to explain how these in turn are influenced by the degree of (concrete) implementation, in the present study we have implemented a detailed analysis of (1) semi-quantitative data about the degree of implementation of the FIT64b specific components and (2) qualitative data on the experiences of FIT64b implementation and outcomes from a multi-stakeholder perspective. Based on these qualitative analyses, and incorporating a theoretical framework, a logical diagram displaying the change mechanisms of FIT64b models was developed. Semi-quantitative data was used to show how these mechanisms vary according to different FIT64b model implementations.

Setting and Sampling

In 2015, leaders of the 15 psychiatric departments included in the EvaMod64b Project were asked to participate in this study. 13 of them (10 of adult psychiatry and 3 of child and adolescent psychiatry departments) agreed to do so. Due to the lack of comparability with adult psychiatry, child and adolescent psychiatry departments were excluded from this study and were evaluated separately (22). The 10 participating psychiatric hospitals are located in the German regions of Schleswig-Holstein (Heide, Itzehoe, Rendsburg), Saxony (Glauchau), Thuringia (Nordhausen), Lower Saxony (Lüneburg), Hesse (Riedstadt), Berlin (districts of Kreuzberg and Neukölln), and Brandenburg (Rüdersdorf).

In each of these psychiatric departments, SU, caregivers and hospital staff members were selected for participating in the qualitative study, whereas semi-quantitative data were collected only from hospital staff members. As the focus of this study is mainly on process rather than – or only to a limited extent – on outcome evaluation, a larger number of hospital staff participants in comparison to SU and caregivers were recruited.

Participants were selected purposely in order to ensure the highest possible heterogeneity (especially within the focus groups). This was ensured by a study employee on site, who recruited participants using a sampling plan containing a precise description of the selection criteria (see Supplementary Material, Table S1). For instance, staff members who had worked within a FIT64b model for a long as well as only for a short time were included. Accordingly, SU and caregivers who had made treatment experiences with (specific components of) FIT64b models for a long or a short period of time were selected. SU were included in the study only if, at the time of the survey, they were not in an acute phase of illness and if they had enough German language skills. Caregivers were selected with and without reference to the participating SU. Generally, participants were directly approached by the study employee and according to the selection criteria defined in the sampling plan. Sampling was continued until data saturation was met (see Qualitative Data Collection and Qualitative Data Analysis). The number of all participants approached in the qualitative study and the number of individuals who denied participation or dropped out have not been monitored. Further details concerning the inclusion criteria of the study participants can be found in the first publication on this project (11). The study was approved by the Ethics Committee of the Brandenburg Medical School (2016, No. S 7 a) and was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. All participants gave their informed written consent.

Assessment of Semi-Quantitative and Structural Data

Semi-quantitative data about the degree of implementation of each FIT64b specific component was captured using a standardised questionnaire (12), which was developed within the scope of this project and was filled in by the managerial staff of each psychiatric department. The operationalization of each component was quantified and thus measured on a rating scale (see **Table 1**). Further methodological remarks on the grading process have been published elsewhere (11, 12). In addition, structural data (including basic data about the hospitals' catchment areas and funding approaches) were requested (see **Table 2**).

Qualitative Data Collection

Figure 2 gives an overview of the qualitative research process. We used different formats to collect in-depth qualitative data. First, expert interviews were conducted especially with program managers and chief physicians in 10 study departments. This may be considered as appropriate for a comprehensive description of the implementation process of FIT64b models, since expert interviews enable to "address a potential interview partner in a specific role, as he or she has access to knowledge that is not exclusive but not accessible to everyone in the field of action" (23). Second, focus groups were conducted to examine changes in treatment practice, culture and ethos and perceived effects. The group process aims to overcome subjective rationalizations and psychological barriers and to uncover underlying beliefs and ideas (24). To

TABLE 1 | FIT64b model components and their operationalization according to von Peter et al. (2019).

No.	Component	Operationalisation	Assessment
I	Shifting in- to outpatient setting Shift of treatment from I ¹ toward D ² and/or O ³	Number of outpatient CoT ⁴ /total number CoT ⁴ during EP ⁵	
II	Flexible care management across settings Unproblematic shift of SoT ⁶ (prompt, little bureaucracy)	 Number of CoT⁴ using all three SoT⁶ during EP⁵/total number SoT⁶ Treatment D², 1¹, and/or O³ in the same unit (ward, level etc.) Systematic steering of treatment beyond all SoT⁶ Application of SoT⁶ spanning roster and therapy plans Number SoT⁶-spanning sessions (meetings etc.) 	Rating scale (0-2) Rating scale (1-3)
III	Continuity of treatment team Implementation of team- and individual- related continuity	 Percentage of staff working in more than one SoT⁶ (on a regular basis) Coordinated admission (coordinating staff member) Coordination of treatment by e.g. case manager, SoT⁶-spanning care Home treatment by I¹- and D²- teams Outsourced PIA (outpatient department) team (not working in I¹ or D²) 	Rating scale (0-2)
IV	Multiprofessional cooperation Intense multiprofessional cooperation	 Absolute number of mandatory sessions across all occupational groups Measure/action to optimize cooperation across all occupational groups Training sessions multiprofessional cooperation Number occupational groups working in home treatment (on a regular basis) 	Absolute number Rating scale (0-1) Rating scale (0-2)
V	Therapeutic group sessions across all settings Therapeutic groups with members from all SoT ⁶	Number of group sessions open for all SoT ⁶	Rating scale (0-2)
VI	Outreach home care Multiprofessional treatment at home ≥ 1 week	 Number CoT⁴ with home-treatment/all I¹-cases during EP⁵ Cars for home-visits 	Rating scale (0-2)
VII	Involvement of carers Caregivers as therapeutic tool	"Network" or other forms of systemic dialog with caregivers and/or "carer-conference" and/or "caregiver groups" Number of groups open for carers	Rating scale (0-1)
VIII	Accessibility of services Geographical accessibility and accessibility of teams	 Percentage of systemic training for staff/employees (e.g. open dialogue) Accessibility of services within one-hour drive 24-hours-accessibility of multiprofessional mental health team (not doctor on call or the like) Shuttle service for services users Waiting list 	Percentage Rating scale (0-2) Reverse rating scale (1-0)
Х	Sovereign steering of services Freedom of therapeutic decisions	 Number of exeats ≥ 2 nights in a row during EP Number of exeats per service user/calendar week during EP D² treatment as well during the night Rules according to contract in all matters concerning setting of treatment and length of treatment 	Rating scale (0-2)
X	Cooperation across sectors Cooperation with ambulant care systems	 Mutual scheduling and realizing of treatment with ambulant care systems (Social Code V) Mutual scheduling and realizing of treatment with social welfare system (Social Code XII) "Community psychiatric network" 	Rating scale (0-2) Rating scale (0-1)
ΧI	Expansion of professional expertise Professionalisation of staff	 Multiprofessional training of staff concerning FIT64b models Measures to multiply knowledge about FIT64b models FIT64b models as part of appraisal interviews 	Rating scale (0-1)
		 F1164b models as part of appraisal interviews Percentage of nurses/caregivers moderating group sessions 	Percentage

^{1,} inpatient; 2D, day-patient; 3O, outpatient; 4CoT, case of treatment; 5EP, evaluation period; 6SoT, setting of treatment (outpatient, day-patient, inpatient).

consistently gain knowledge from a multi-stakeholder perspective, focus groups were predominantly set up with staff, SU, and caregivers.

To carry out the qualitative evaluation (**Figure 2**; *Step I*) a semi-structured interview guideline was developed (see **Supplementary Material, Table S2**), based on the thematic fields of the aforementioned 11 FIT64b specific components.

Data was collected sequentially between April and October 2016 by SP together with one of the co-authors (changing for

each specific site). In this period each of the 10 study departments was visited for 2–3 days. A total of 31 focus groups (2–5 in each department) and 15 expert interviews (1–3 in each department) was carried out. The average duration of the interviews and focus groups was approximately 84 min. Data collection was digitally recorded, transcribed verbatim, and anonymized. The analysis process started while data was still being collected. Regardless of the occurrence of theoretical saturation, data collection was performed in all departments.

TABLE 2 | Structural data of the psychiatric departments, including socio-geographic data of the corresponding catchment areas and data about hospital funding (year: 2016).

	Hospital departments									
	Α	В	С	D	E	F	G	н	I	J
Catchment area										
Settlement	rural	rural	rural	rural	urban	urban	metropolitan	metropolitan	urban/ rural	rural
Population density (inhabitants per km²)	124	93	124	119	342	525	13.819	7.301	665	95
Inhabitants (in tousand inhabitants)	131	135	270	85	130	330	281	328	425	235
Hospital funding										
Sponsorship ¹	public	public	public	public	non-profit	public	public	public	public	non-profit
Contract closing date; Start of FIT64b implementation	2014-1	2013-1	2013-1	2014-1	2013-1	2016-1	2016-2	2016-1	2014-7	2014-1
Budget share (%) ²	100	100	100	100	100	100	10	8,5	33	25
Experiences with similar funding approaches ^{3,4}	+	+	+	+						
Reduction of hospital beds since introduction of a GTB ^{4,5}	+	+	+	+	+				+	

¹Public or non-profit hospital organisation; ²Portion of the hospital budget which is negotiated according to §64b Social Code V with a selection or all involved health insurances; ³Existing experiences with a Global Treatment Budget according to §24 "Bundespflegesatzverordnung", the §64b preceding legislation, valid from 2002-2009, offering hospitals a fixed annual budget for the duration of 5 years; ⁴Maximum expression of parameter = +; ⁵GTB, Global Treatment Budget.

Theoretical Framework

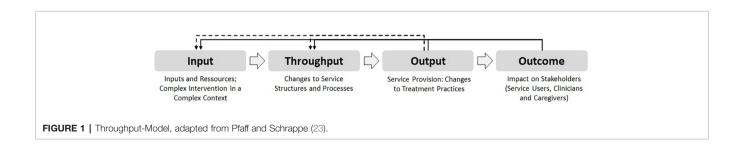
Among various theoretical models that have been applied within this research field (see, e.g., 25), we selected the German Throughput-Model by Pfaff and Schrappe (26, 27) as a guiding framework due to its compatibility with the aims and nature of this study. Pfaff and Schrappe's (26) model draws on Donabedian's Structure-Process-Outcome theory (28), and it provides a solid and helpful framework for describing complex interventions, for clarifying their causal assumptions and for developing a program theory. **Figure 1** depicts a basic diagrammatic representation of the relationships between an intervention's *Input*, *Throughput*, *Output*, and intended *Outcomes* according to Pfaff and Schrappe (26).

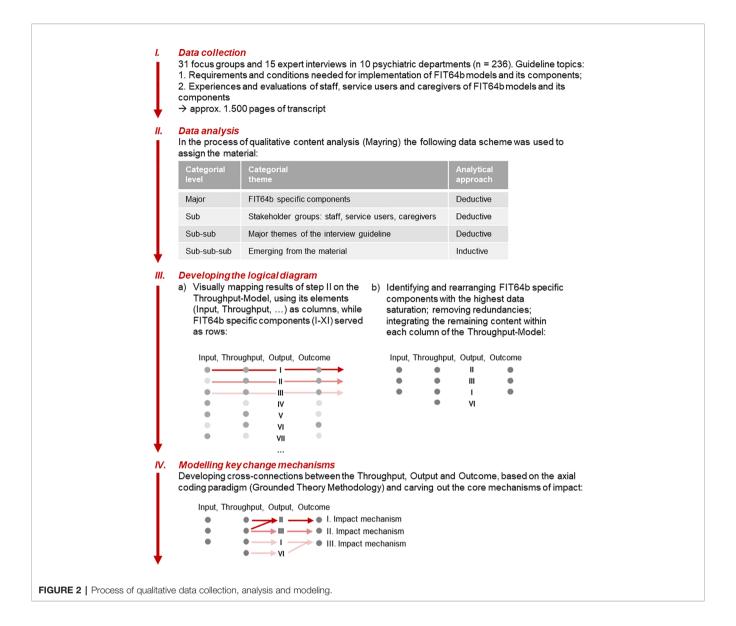
Input does not only include the concrete resources needed to realize an intervention, but it also involves changes in regulations and conditions within the wider context of the health care system. These contextual factors may be interventions at system's level that, for instance, are followed by changes in hospital remuneration or legislation. Throughput describes changes in the structures and processes of an intervention (29) and Output corresponds to the level of service provision; it describes for example professional behaviors, organizational change, and possible changes within the health care system. Outcome describes the results of an intervention both at the stakeholders' and system's levels (27). Going beyond Donabedian's unilateral concept, the Throughput-Model puts forward a more systemically informed understanding of

interventions: indeed, here, *Outcome* and *Output* are conceived as having a feedback function on *Input* and *Throughput*.

Qualitative Data Analysis

The first analytical step (Figure 2; Step II) was guided by the rulebased approach of content analysis (Mayring) (30, 31). We chose this methodology, because it provides a solid framework to transform great amounts of qualitative data into a more compact and reduced form yet conserving the original richness of information. Due to the extent of the material (approximately 1,500 pages of transcript) and in order to increase reliability, data were thematically split within the research team: Tandems of two researchers examined the material of each stakeholder group (SU, carers, staff) adopting a mixed deductive-inductive approach (Figure 2; Step II). In the process of content analysis, the specific components of FIT64b served as deductive major categories and analytic grid to which the qualitative material was assigned. Subsequently, the requirements and conditions needed for implementation of FIT64b models, the perceived changes in treatment practices, culture, and ethos and the effects of FIT64b models were analyzed and developed into further categories (Figure 2; Step II). Throughout this process the paired researchers (tandems) continuously met to discuss and to reach agreements on the intermediate and final categories. The full research group also worked together in several analytical workshops ("Forschungswerkstatt") to triangulate and validate results.





Logical Diagram and Key Change Mechanisms

In order to develop a logical diagram describing common aspects of FIT64b model implementation, JS and SP mapped the results of the prior analysis onto Schrappe and Pfaff's theoretical framework (**Figure 2**; *Step IIIa*) (26). In this process, the elements of the Throughput-Model (Input, Throughput, Output, Outcome) were used as columns, whereas the 11 FIT64b specific components served as rows. The results from the previous analytical step were thus gradually placed and arranged on this grid. Due to the great extend of the data the logical diagram had to be reduced, integrated, redundancies were removed and only those FIT64b specific components that showed the highest data density within the logical diagram were left (**Figure 2**; *Step IIIb*): These components were: (I) shifting from in- to outpatient settings, (II) flexible care management across settings, (III) continuity of treatment team, and (VI) outreach care. This is in accordance

with the published results of a previous pilot study and with the quantitative findings of the EvaMod64b project, thus indicating that these four components can be considered as key aspects of FIT64b models (12, 32).

In a final analytical step (**Figure 2**; *Step IV*) we started searching for cross-connections between the elements of the Throughput-Model, applying the axial-coding paradigm of Grounded Theory Methodology (33). In an iterative process, three common impact mechanisms of FIT64b models could be carved out, leading from the Throughput to the Output and Outcomes. For the sake of clarity, change mechanisms were only made visible at the Throughput-level, because all elements of the Input and of the Throughput diverged from one another. During this analytical process, preliminary versions of the logical diagram were validated by the entire research team. Their suggestions for revisions were considered and the model was changed accordingly.

TABLE 3 | Implementation of FIT64b key components in the psychiatric departments (year: 2016).

FIT64b key components	Hospital departments									
	Α	В	С	D	Ē	F	G	Н	I	J
I: Shifting service users from in- to outpatient settings										
Number of outpatient CoT ¹ /total number SoT ² during EP ³ (%)	55,77	47,22	32,29	61,37	53,10	69,93	71,88	x^4	60,62	43,37
II: Flexible care management across settings										
Treatment D^5 , I^6 , and/or O^7 in the same unit (ward, level etc.) ⁸	++++	++++	++	+++	+++	++		++	++	++
Systematic steering of treatment beyond all SoT ^{2,8}	+++	++++	++	+	+	+	+	+	+	++
Number SoT ² -spanning sessions (meetings etc.) ⁸	++++	++++	++		+++	++		+	++	+
Application of SoT ² -spanning roster and therapy plans ⁸	++++	++++	++	++	++++	++	++	+	+++	++
III: Continuity of treatment team										
Percentage of staff working in more than one SoT ²	>66%	>66%	>66%	>33%	>66%			>66%	>33%	>33%
(on a regular basis)										
Coordinated admission (coordinating staff member) ⁹		+	+	+			+		+	
Coordination of treatment by e.g. case manager ⁹		+	+	+	+			+	+	
Outreach home care by I ⁶ - and D ⁵ -teams ¹⁰	+	++	++		+				+	
Outsourced outpatient department team	+									
(not working in I ⁶ or D ⁵) ⁹										
VI: Outreach home care										
Implementation of outreach home care ⁹	+	+	+	+	+		+	+	+	
Corresponding outreach care model ¹¹	ACT	ACT/CRT	ACT	ACT	ACT		CRT	CRT	ACT/CRT	
Number of cars	1	4	2	1	2		2	1	3	

¹CoT, case of treatment; ²SoT, setting of treatment (outpatient, day-patient, inpatient); ³EP, evaluation period; ⁴x, data not provided; ⁵D, day-patient; ⁶I, inpatient; ⁷O, outpatient; ⁸Maximum expression of parameter = ++. ¹¹Assertive Community Treatment (ACT) or Crisis Resolution Teams (CRT).

RESULTS

Semi-Quantitative Findings

The semi-quantitative findings about the degree of implementation of FIT64b specific components are presented in **Table 3**. As the qualitative material presented below is limited to the key components (I, II, III, VI), the semi-quantitative findings are also limited to these.

Qualitative Findings

A total number of 63 SU, 35 caregivers, and 138 hospital staff members were interviewed. **Table 4** shows the sociodemographic data of the study's participants.

TABLE 4 | Participants' sociodemographic data.

Stakeholder group	n (%)	Female gender n (%)	Additional parameters
Service user	63 (26.7)	36 (57.1)	Ø 6,8 years duration of illness; n=24 (38.1%) currently in psychotherapeutic treatment; all psychiatric diagnoses were included with a focus on various forms of schizophrenia spectrum disorder
Caregiver	35 (14.8)	21 (60.0)	Ø 6,7 years duration of treatment of the respective relative; different kinds of caregivers were included, with a majority of mothers.
Staff	138 (58.5)	82 (59.4)	n=90 (65.1%) have worked in the same psychiatric department before the introduction of the GTB; n=48 (34.9%) had been working in other psychiatric hospitals before the introduction of the GTB.

GTB, Global Treatment Budget.

As a result of content analysis, we carved out 5 core themes related to the implementation of the FIT64b, which were mapped onto the Throughput-Model (see **Figure 3**). The first three themes were labeled: (I) FIT64b resources and inputs; (II) Changes to hospital structures and processes; (III) Changes to treatment practices. Since these themes have a mainly descriptive character, we did not deem it necessary to report quotes from the transcripts. The last two themes were labelled: (IV) Impact on staff, treatment culture and ethos; (V) Impact on service users and caregivers. These themes entailed an evaluative aspect and are thus supported, in the presentation of results, by textual quotes from the transcripts.

Theme 1-FIT64b Resources and Inputs

In all the participating psychiatric departments, staff reported that the initiative to enter a contract according to §64b (German Social Code) came from both psychiatric hospitals and health insurances. Health insurance companies were often motivated by the prospect of controlling costs, whereas clinicians saw the possibility of maintaining predictable and constant compensation, which would facilitate the further development of psychiatric services.

Changes to Hospital Reimbursement

All the participating hospitals negotiated a fixed, lump-sum budget per annum (GTB) dedicated to financing the acute psychiatric care provided by either all or by only specific health insurances for a maximum term of 15 years. Compared with the usual performance-based remuneration in psychiatric hospitals, which leads to an increase in bed occupancy to maximize remuneration, a GTB would strengthen the tendency to act more proactively or preventively in order to avoid high resource usage.

Shifting Resources

Large parts of the hospital budget, which had previously been used to finance inpatient treatment structures, were moved to the

Input

Theme 1: FIT64b resources and inputs

Changes to hospital reimbursement: Switching from per-diem payment to global treatment budget in hospital-based mental health services for a limited episode of 8 years.

Shifting resources: E.g. from in- to outpatient hospital budget share.

Reinvesting budget savings: Developing innovative treatment offers (integrated and outreach care, day- and night-clinics) and therapeutic elements (e.g. animal-assisted therapy, open dialogue); informing and training staff about the changes in reimbursement and treatment offers.

Throughput

Theme 2: Changes to hospital structures and processes

Hospital information system that includes all treatment settings

Integration of treatment settings in a hospital ward: Reduction of inpatient beds, merging of inpatient units, scaling up outpatient treatment spaces.

Transforming inpatient- to setting-flexible treatment teams: Staff training about application and recombination of new treatment to practices; defining rules for changes of setting; dissemination of therapeutic attitudes necessary for cross-sectorial treatment and outreach care ("thinking outpatient").

Implementing infrastructure for outreach home care: Building up transportation infrastructure, staff recruitment and training.

Output

Theme 3: Changes to treatment practices

Flexible care management across settings (II): Facilitated change of setting, discharge and readmission; reservation of hospital beds for patients switching between settings.

Continuity of treatment team (III): Implementation of teamand person-related continuity of care across different settings.

Service users shifting from into outpatient settings (I): Offering complex outpatient treatment during acute crisis as alternative to inpatient treatment.

Outreach home care (VI): Home treatment, delivered by a multi-professional, flexible team, more then once a week

Outcomes

Theme 4: Impact on staff, treatment culture and ethos

Relief through more freedom in therapeutic decisions: Being able to choose from a broader spectrum of therapeutic options (e.g. settings, therapy elements).

Less bureaucracy and organisational effort

Closer relationship and better understanding of service users in Accompanying service users in the different settings and phases of the recovery process; more information about users' life situation.

Change of therapeutic attitude: Trusting and giving more autonomy to service users.

Higher job satisfaction:
Job variation, more expertise,
less bureaucracy, closer
relationship to service users.

Theme 5: Impact on service users and caregivers

Treatment fits better to ones' needs: Receiving low threshold support, tailored in terms of time, location and intensity; more self-determination.

Deeper understanding, trust and feeling of safety: "Not having to repeat ones' story again and again"; "staff knows me"; helpful function of relational continuity in acute

Closer to everyday life: Spending time with family, and social network; rebuilding relationships; higher demands in terms of self-structuring to

FIGURE 3 | Logical diagram of FIT64b models, at once categorial system of the present qualitative process evaluation. I, II, III, VI: the Roman numerals refer to the key components of FIT64b. All FIT64b specific components can be found in **Table 1**.

outpatient sector. Since the average daily costs of inpatient care are significantly higher than those of outpatient treatment, hospitals could increase the intensity of outpatient work without having surplus costs.

Reinvesting Budget Savings

Hospitals reinvested the saved budget shares in order to act in accordance with the legislation. Study participants expressed quite different opinions about the use of saved budget shares. In general, these were invested for the further development of hospital structures (e.g., for outreach and integrated care, day and night clinics), for developing new therapeutic offers (e.g., animal-assisted or art therapy), or for training hospital staff (e.g., training in the systemic approach of Open Dialogue) (34).

Theme 2—Changes to Hospital Structures and Processes

In what follows, we present the key changes to hospital structures and processes, which were based on the intervention inputs and which were realized across all the participating psychiatric departments.

Hospital Information System That Includes All Settings

The hospital information system (HIS), which had so far processed in- and outpatient treatment separately, was merged to assure that (1) the clinical and performance documentation of each treatment setting could be accessed by the other settings and (2) patients could easily and flexibly shift from one setting to the other.

Integration of Treatment Settings in a Hospital Ward

In order to structurally integrate out-, day-, and inpatient treatment within one unit, areas that were previously used for patients' rooms were transformed into outpatient recreation and therapy rooms. As FIT64b models progressed, the proportion of patients treated in integrated out- and day-settings increased so that areas dedicated to inpatient treatment could be further reduced and inpatient wards could be closed or merged. Such restructuring was primarily implemented by the psychiatric departments A–D, that negotiated their entire hospital budget as a FIT64b model and that had prior experiences with a GTB. In three departments (A, F, J) new buildings were constructed in order to meet the FIT64b requirements and to allow the separation of sleeping and recreation areas, which were previously joined.

Transforming Inpatient- to Setting-Flexible Treatment Teams

Before the introduction of the FIT64b model, each staff member's clinical work was restricted to *one* setting. This regulation was dropped with the introduction of FIT64b: "setting-specific" teams were restructured into "flexible teams," acting across all treatment settings (departments A–D). Therefore, processes and clinical routines, such as, planning therapies, shifted from being performed within specific settings to being extended across them. In FIT64b models, employees working on an inpatient ward kept flexible time slots available for outpatients. The departments (G–J) that introduced a GTB for just a part of their SU (less than ½

budget shares) tended to retain traditional team structures and established additional dedicated teams to exclusively attend to these SU.

To support these transformations, employees received several trainings aimed at promoting favorable attitudes toward "flexible and outpatient thinking." Given that most staff members were trained within traditional hospital wards, a new approach toward mental health crises had to be introduced and taught. An important part of this process was the definition of clear and stable criteria for the change of setting, in order to facilitate the organisational change from a highly structured single-setting treatment, to a more unbound therapeutic work across settings.

Implementing Infrastructure for Outreach Home Care

Several structural requirements had to be fulfilled in order to allow the introduction of outreach forms of care. A business plan was needed in order to proof the feasibility of outreach home care within the hospital budget (share). New equipment, such as cars and mobile phones, was acquired and new solutions for mobile documentation and synchronisation with the HIS were developed. In rural catchment areas (clinics B–D, I) cars were purchased, whereas urban teams also used bicycles or public transport (clinics G, H). Employees received specific training for outreach work. Outreach work was realized either by (flexible) inpatient teams (clinics A–E) or by dedicated teams (clinics G–I). Due to extensive requirements, the component "outreach home care" was introduced with a delay of one to two years in the FIT64b model runtime.

Theme 3—Changes to Treatment Practices

The interaction of input and throughput factors lead to changes in service provision and treatment practices. These changes are best described by the developed processual and structural components of FIT64b models (**Table 1**). As mentioned above, we here only present 4 key components (I, II, III, VI) that reached data saturation during the process of thematic analysis. The reference to each specific component is indicated in the subheadings.

Flexible Care Management Across Settings (II)

Based on the GTB, new forms of support were introduced that involved flexible "degrees" of treatment intensity and the possibility for SU to flexibly shift between settings. As a result, SU who mistrusted inpatient psychiatric treatment could be slowly introduced to it by gradually increasing the treatment intensity. Furthermore, the increased overlaps between treatment settings allowed more flexible transitions to a SU's own home or workplace after inpatient care by gradually reducing the days or time of treatment (instead of ending it abruptly). The psychiatric departments A and B reserve inpatient beds during the phase of outpatient care to allow for a rapid admission in case of symptoms worsening. One clinic (J) introduced an acute day-patient setting for an uninterrupted day-treatment (also on weekends), whereas clinic B launched a night-patient setting for SU who need assistance only at night.

Continuity of Treatment Team (III)

The psychiatric departments A–E, which already had experience with previous FIT64b care and reimbursement models, achieved the highest degree of team- and person-related continuity of care

(see **Table 3**). This is organized in various ways: either employees attend to their patients across various settings (departments A–D) – sometimes even in their homes in the case of outreach treatment teams (departments A–C) – or case managers were hired for coordinating the treatment process and thus ensuring continuity (departments B–E). In addition, some of the participating psychiatric departments (E, F) introduced adolescent psychiatry counseling teams, therefore also aiming at enabling smooth transitions into adult mental health services.

Service Users Shifting From In- to Outpatient Settings (I) By integrating in- and outpatient settings, a significant portion of previously inpatient SU is now being treated within various outpatient settings, even during episodes of acute crisis. The psychiatric departments use outpatient facilities to prevent inpatient stays, to offer aftercare and to provide low-threshold access to inpatient forms of treatment.

Outreach Home Care (VI)

Following the introduction of a GTB-based accounting system, eight out of ten participating psychiatric departments currently offer multi-professional outreach treatment. Home visits are delivered on weekdays between 8–18 o'clock. The frequency of home visits (from daily to once every four weeks) and the duration of treatment (from < 2 to > 12 weeks) vary considerably between the departments. Departments in urban catchment areas are more likely to deliver shorter and high intensity treatment, whereas departments within rural areas provide longer treatment periods with less frequent visits.

Theme 4—Impact on Staff, Treatment Culture, and Ethos

Changes to hospital structures, processes, and treatment practices had complex impacts on the treatment culture and on the underlying therapeutic stance of employees.

Relief Through More Freedom in Therapeutic Decisions

The possibility and freedom to combine a broader range of therapeutic options and to take decisions about the course of treatment was described by employees as a relief and as a gain in therapeutic autonomy. By being less bound to the contingencies and restrictions of a specific setting, clinicians could tailor treatment more to the SU's needs:

"So, if someone gets admitted and you notice after 2, 3 days, that he may benefit more from the day hospital setting, then we switch. And when it turns out that it was a bit risky, we can easily go back to inpatient conditions without having to clear up many formalities. This is very relieving for us but also for the patients" (Physician, Department B).

Staff members reported that they are currently free to decide how much time they intend to dedicate respectively to inpatient and outreach work. Hospital staff is also no more accountable for justifying the length of stay or the type of treatment to the health insurances. This also considerably contributed to the feeling of relief on their part. Nevertheless, the employees participating in this study also described adverse effects of the increasing flexibility in the treatment process. In contrast to the therapeutic activities in regular care being usually limited to one setting,

"people [both staff and SU] now have to be familiar with the peculiarities of in-, day-, outpatient and eventually also outreach work at the same time" (Nurse, Department B).

The increasing complexity of therapeutic options has been described by one employee as "stressful freedom" (Nurse, Department B), as it yields more difficult decision-making processes.

Less Bureaucracy and Organizational Effort

The reduction of bureaucracy in FIT64b models played an important role within our data. In particular, the streamlining of documentation routines accompanying changes of setting was emphasized. The spatial integration of the treatment settings facilitated not only the exchange of information among staff but also the performance of everyday routines (by e.g. shortening distances):

"Organizationally, my day was even easier: I do not have to change rooms to go to the day treatment unit or ambulance. I just stay in the same place" (Nurse, Department A).

In contrast, the organisation of group therapy sessions across all settings was described as a challenge: Since SU from different settings participated in the same group sessions, these groups were sometimes experienced by staff members as being too heterogeneous. Consequently, staff members reported difficulties in keeping track of the different setting (e.g., who is inpatient or outpatient) and in integrating participants with different needs.

Closer Relationship and Better Understanding of Service Users

The continuity of treatment across different settings promoted more stable relationships with SU and more comprehensive understanding of them and of their situations. This results from the fact, that SU are currently attended by the same therapist or therapeutic team during longer treatment episodes (both in- and outpatient), and not only during moments of acute crisis:

"There's quite another level there, a level of trust and you do not have to start from scratch again. When the patient changes to day or outpatient treatment, you may discover a lot more about his or her resources, of which you then also may make use of. And this makes the treatment process more intense" (Social worker, Department A).

This allows staff members to attend to their patients through the different stages of the recovery process, thus supporting and facilitating the co-construction of shared solutions for complex problems. Yet, the trade-off of continuity is an increased difficulty in ending the therapeutic relation for both staff and SU:

"Some patients don't find it easy to say goodbye to their reference therapist at the end of treatment. For longer courses, we therefore try to plan discharge at an early stage" (Psychotherapist, Department C).

Expanding therapeutic continuity beyond inpatient treatment to outreach and outpatient settings also allowed employees to develop a deeper understanding of the SU's life situation. In this regard, caregivers played an important role as sources of information, often empowering and mediating the relationship between SU and the treatment team.

Change of Therapeutic Attitude

Driven by the broader and more flexible spectrum of therapeutic options available and by the stronger therapeutic alliance, employees described an increased tendency to leave SU more autonomy:

"Over the past few years we began to discharge patients earlier. Thereby, we have increasingly developed trust even to rather unstable patients – to clients that we would have kept in the ward in the past" (Nurse, Department B).

Employees' stronger orientation at outreach and outpatient care also contributed to their increased reliance on SU's competencies and resources:

"I've been thinking a lot about how to improve my patients' resources. The more resources you develop during the patient's inpatient stay, the greater is the likelihood that an outpatient setting will work for him or her" (Psychologist, Department J).

Finally, the attitude toward caregivers also changed: caregivers are currently involved as active partners since the early stages of the treatment process instead of being considered as a mere source of information:

"Relatives are less likely to be a resource on the ward and this is reversed in the home environment" (Nurse, Department G).

Higher Job Satisfaction

Overall, employees were satisfied with the new work models. They mentioned an increased motivation that resulted from their active involvement within this innovative model of treatment. For instance, additional therapeutic tasks were assigned to professional groups that traditionally did not work therapeutically. Such changes were perceived to increase therapeutic expertise, especially among the professional group of nurses. Yet, the increasing complexity of care pathways also led some employees to feel overwhelmed. Other employees critically noted that the additional therapeutic tasks were not

appropriately remunerated. In general, however, employees' expressions of satisfaction outweighed their criticisms:

"To be able to accompany a person through various phases: I experience this as enriching for me personally, but also for my profession. To accompany development, to see people grow. To see them going through crises, and still seeing that life goes on" (Physician, Department B).

Theme 5-Impact on Service Users and Caregivers

Changes to the treatment practices, the treatment culture and the underlying therapeutic stance of employees has led to several effects on SU and caregivers, which are described below.

Treatment Fits Better to One's Needs

From the SU's point of view, the increased flexibility of treatment in FIT64b models also led to its better adaptation to their needs. For instance, SU experienced treatment to be less oriented by institutional routines and instead to be more shaped around the concrete needs of their work or family life. Being granted the possibility to participate in decisions about when, where and at which intensity one gets support, seemed to relieve SU. A key factor within this sub-theme was the importance of and the preference for low-threshold support in acute situations:

"With this [FIT64b] model, it was very flexible. I could say 'Tomorrow I'll come from then till then' or 'I'd rather sleep here [in the hospital]'. I could always just look and ask myself 'How is it? What do I need now?' And then I got exactly the right help" (SU, Department B).

"There was a note on the bed' Ms. X'. And if for once I could not handle a day at home, I could just move in here again" (SU, Department A).

Deeper Understanding, Trust, and Feeling of Safety

Mirroring and confirming employees' experiences (see Theme 4.2), SU and caregivers reported having felt better understood by the staff due to the continuity of treatment. This was experienced as a relief ("not having to repeat ones' story again and again"; SU, Department C). The awareness of having a constant reference therapist (or team), who is well informed on the situation and on what might help during crises, yielded feelings of trust and safety in SU and caregivers.

Comparable experiences were also reported by SU, who received outreach care: "One feels safer at home than here in the hospital" (SU, Department I). Therapy time felt more intense within outreach forms of care; it was perceived by SU as being characterized by greater and more "undivided" attention by professionals, if compared to the inpatient setting. Furthermore, outreach care led to a change of traditional roles (patient as host; therapist as guest) that enabled more balanced power relations:

"We spent some time hanging around in the kitchen together. This is my favourite place to sit and talk, whether for tea or for dinner. And that gave me the feeling, that yes, one speaks to me at eye level" (SU, Department H).

Closer to Everyday Life

A key outcome of FIT64b, defined by SU and caregivers, was the fact that this treatment model allowed them to carry on with their everyday-life activities also during moments of acute crisis:

"That I can keep my usual environment and continue my everyday life while being treated at home, that is the most important thing" (SU, Department G).

Especially, integrated outpatient and outreach forms of care made it easier for SU to stay in contact with their social and family networks and to return to work even during treatment. Yet, the lack of distance to one's own personal background and social sphere, the lack of a given structure and of distractions, the feeling of isolation and the need for self-organisation also during acute crises were described as challenges by some SU, who were treated at home:

"It is not always easy for someone like me, who doesn't have enough daily structure. Of course, the flexible [home treatment] team brings some routine into your life, depending on how often you need it" (SU, Department G).

Caregivers were quite ambivalent about the integration of everyday life in FIT64b models. On the one hand, they experienced home treatment as an advantage, as it allowed them to be present during therapeutic sessions and to contribute to the recovery of their kin. On the other hand, this gave them an additional responsibility that sometimes was described as a burden. Both patients and caregivers first had to get used to the intrusion of the hospital staff in their personal spaces and to the associated experienced loss of possibilities for retreat. Yet, as they became more acquainted with the benefits of outreach care, their initial reservations gradually diminished.

DISCUSSION

The main objective of the present work was to examine the impact of implementing an integrative, GTB-based model of psychiatric care on SU, caregivers and employees.

Based on the stakeholders' experiences, a logical diagram was developed (**Figure 3**) to illustrate the implementation process from its inputs to its outcomes. Although the underpinning Throughput-Model (**Figure 1**) is rather linear in structure, it includes contextual factors (e.g., legal frameworks, remuneration systems) and systemic effects (such as feedback mechanisms) (27, 28). Accordingly, by using the Throughput-Model we aimed at overcoming traditional evaluative approaches that reduce intervention outcomes to only few parameters (35), thus examining the impact that GTB-based FIT64b models may have on the broader context of the stakeholders' lives. As

shown above, the provision of care did not only affect SU and their caregivers but it also influenced the overall treatment culture and ethos: It resulted into a changed practice of dealing with acute crisis situations among staff, leading to a more confident and autonomy-promoting attitude.

In what follows, we first discuss the impact that a GTB may have on implementation and practice within FIT64b models. Second, we present key impact mechanisms within the developed logical diagram (**Figure 4**) by integrating the results of our qualitative analysis with the related literature. Third, we illuminate how the identified change mechanisms vary between the two prototypes of FIT64b implementation by taking into account both the semi-quantitative and the structural data of the involved hospitals.

Impact of Global Budget Approaches

Our findings describe how integrated psychiatric care was gradually built-up, based on the financial securities provided by a GTB. This would not have been possible under the conditions of the common day- and performance-oriented reimbursement system of German hospital care (8). The GTB allowed to reallocate to outpatient settings the now unutilized inpatient hospital structures and to employ former inpatient staff in outpatient and outreach services (35). We showed that the reallocation of FIT64b resources in proactive and preventive ways allowed to avoid intensive forms of treatment and thus, to save expenses on the long-term. These results align with findings by the British Medical Association stating that financing approaches similar to GTB, like capitation payment, encourage greater investment in the secondary or tertiary preventive and community-based care because they allow to flexibly allocate

resources so as to produce the best possible outcomes for SU (6, 7).

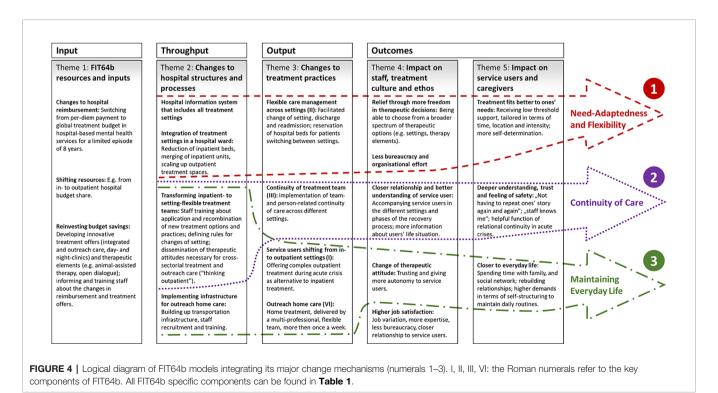
Modeling Key Change Mechanisms

With the development of the logical diagram (**Figure 3**) it turned out that almost each throughput factor can be connected *via* the outputs to the outcomes. This explains which aspects of the throughput are fundamentally responsible for which outcomes. **Figure 4** shows the previously developed logical diagram including three key change mechanisms. These are: (1) Need-Adaptedness and Flexibility, (2) Continuity of Care, and (3) Maintaining Everyday Life. In what follows, we discuss these three central lines of impact, including the related existing literature. This procedure adheres to the recommendations of the MRC framework for evaluating complex interventions, which indicates the necessity of both empirically and theoretically grounded modeling (20).

Need-Adaptedness and Flexibility

One key mechanism of our logical diagram is the positive impact of the increased flexibility of treatment on the need-adapted nature of care within FIT64b models (**Figure 4**). The integration of settings and teams and the simplification of bureaucratic processes allowed SU to swiftly shift between settings and, thus, to be treated more according to their needs. These findings align with the definition of flexibility put forward by other team-based care models such as the Dutch flexible ACT (36), which mainly relies on the idea of adapting the treatment intensity to the concrete needs of SU.

Our results thus show how the primarily economic flexibility of a GTB was directly passed onto the everyday structure of the



services and to the SU themselves (6, 7): For instance, by eliminating the economic constraint of occupying inpatient beds, the hospital departments were able to keep spare beds available in case a SU needed to be readmitted. Our participants evaluated this as a significant increase in need-adaptedness.

Continuity of Care

Relational continuity emerged from our results as a fundamental factor of flexible and integrated psychiatric care according to \$64b Social Code V (Figure 4). The transformation of settingspecific teams into setting-flexible ones supported the establishment of longer-term, trusting relationships between SU and teams (or team members). This, in turn, fostered feelings of trust and safety in SU (36). Our findings align with the ones of previous studies, which have shown a positive correlation between relational continuity and SU's clinical outcomes or satisfaction (37-39). In contrast, Giacco et al. (40) conclude from a one-year observational study that patients treated by the same psychiatrist in different settings do not show better outcomes than those treated by different clinicians. Based on our findings, we argue that SU benefit from relational continuity even beyond measurable clinical outcomes. On the one hand, recovery processes are complex and highly individual and therefore cannot be solely captured by clinical measures. On the other hand, both our and the already existing research emphasizes that many positive effects of a continuous therapeutic connection might be only measurable after a longer period of time (39, 41).

Maintaining Everyday Life

The third causal mechanism of our logical diagram describes how outpatient or outreach treatment services in moments of acute crisis may strengthen the SU' integration in their everyday life (**Figure 4**). This aligns with the results of several evaluation studies on CRT teams, confirming that SU prefer outreach programs over inpatient treatment (42). Another important finding is that all involved stakeholders initially have to get used to this form of treatment: Employees have to be sufficiently trained to be able to carry out home treatment safely and independently and the SU and their families have to get used to the staff "invading" their privacy (42). Yet, as much as SU and caregivers showed initial scepticism about new forms of outreach care, this scepticism mostly faded away during the course of treatment (13).

Two Prototypes of Implementation

The comparison of semi-quantitative data between the psychiatric departments participating in the study demonstrates the heterogeneous implementation of FIT64b models across Germany. This heterogeneity especially emerges from the differences across the involved departments in implementing the FIT64b's key components (see **Table 3**) (12, 14). This is not surprising since the given legal framework includes very vague specifications regarding the concrete implementation. With the goal of systematizing these differences, we have derived from the results two prototypes of FIT64b implementation (see **Table 5**). Hospitals E, F, and J could

TABLE 5 | Two prototypes of FIT64b implementation.

Characteristics:	Prototype:	I	II
Study departments/municipalities Population Density ⁷		A, B, C, D low	G, H, I high
Contract closing date; Start of FIT64b im	plementation	2013	2016
Budget share (%) ⁸		100	<33
Existing experiences with a GTB ^{5,9}		+	
Reduction of hospital beds (occupancy) s a GTB ⁵	since introduction of	+	
Treatment D^2 , I^1 , and/or O^3 in the same etc.) ⁶	unit (ward, level	+++	+
Staff working in more than one SoT ⁴ (%) Outreach home care by I ¹ - and D ² -teams	s ⁵	>66 +	>33
Corresponding outreach care model		ACT	CRT

GTB: Global Treatment Budget; ACT: Assertive Community Treatment; CRT: Crisis Resolution Teams; " ": Not applicable; 1, inpatient; 2D, day-patient; 3O, outpatient; 4SoT, Setting of treatment (outpatient, day-patient, inpatient); 5 Maximum expression of parameter = ++; 6 Maximum expression of parameter = +++++; 7a high population density is reached from a limit of 600 inhabitants per km²; 8 ratio of health insurances (i.e., SU) who joined the contract according to \$64b Social Code V in relation to the whole hospital budget (all SU treated in the hospital); 8 existing experiences with a GTB according to \$24 Bundespflegesatzverordnung", the \$64b preceding legislation, valid from 2002-2009, offering hospitals a GTB for the duration of 5 years.

not be included because they do not fully meet the characteristics of either prototype.

Hospitals aligning with type I are mostly located in rural areas, provide treatment according to FIT64b to all SU (100% budget share) and have collected several years of experiences with similar models of care and reimbursement. Since hospital routines were entirely switched to FIT64b, changes in health care provision are more comprehensive in these hospital departments (especially departments A and B): Out-, day-, and inpatient settings are integrated both in terms of spaces and personnel in almost all units of these departments. Thus, relational continuity is highly implemented and also partially extends into outreach care. Outreach care is predominantly provided over longer periods of time, with rather low treatment intensity, and thus most likely aligns with ACT teams. In general, extended catchment areas with large average distances between hospitals and SU's homes make the implementation of an intensive outreach treatment model hardly feasible (1).

Study departments of type II are situated in urban areas. They did not have previous experiences with a GTB or similar models of care. Those departments only treat a small percentage of SU according to FIT64b (budget share of less than 33%), whereas the vast majority of SU receives treatment as usual (budget share of at least 67%). Thus, two different models of care are kept running simultaneously, leading to friction losses and to limited degrees of implementation of the FIT64b specific components (15). Outreach care is here usually set up in the form of separate teams, providing a rather short-term, acute care, which is comparable to the CRT model (43). Consequently, there is only a slight continuity of treatment teams from the outreach to the inpatient setting.

One of the main reasons for the limited participation of health insurances and thus for the underdevelopment of FIT64b models in urban catchment areas is the problem of risk adjustment of capitated or global budgets (44). In metropolitan areas there is a

much higher exchange of SU between neighboring catchment areas. If a SU "belonging" to the catchment area of a capitated hospital X is treated in another hospital Y, this complicates reimbursement, thus making the implementation of FIT64b models more challenging than in rural areas.

To summarize the differences between the two prototypes with regard to the previously identified impact mechanisms, it can be concluded that 1) hospitals which contracted their entire budget as a FIT64b model do provide a strong manifestation of all three impact mechanisms (see **Figure 4**), whereas 2) hospitals which negotiated a FIT64b model only for a small budget share (less than 33%) have a focus on keeping SU out of the hospital, i.e., maintaining their everyday life.

Strengths and Limitations

A strength of this process evaluation study is that the impacting mechanisms of FIT64b were modeled both empirically and theoretically. This arguably, leads to a realistic understanding of FIT64b models and their implementation (20). A blind spot of this study may lie in the fact that the outcome evaluation was performed prior to the process evaluation (20). This goes against the MRC Guidelines on the evaluation of complex interventions, which recommend to first explore change mechanisms (process), in order to support the selection of measures suitable for outcome evaluation (20). We acknowledge this limitation and yet we believe that, since we used primarily qualitative and iterative analysis methods, we could still achieve an integrated form of evaluation for process and outcome.

A further limitation might be a possible selection bias, since the statements made by the study participants revealed a rather consistently positive view about GTB and FIT64b. One might indeed argue that possible adverse effects of GTBs such as "cherry picking" low-risk SU, "dumping" high-risk ones or an underprovision in order to minimize costs haven't been properly represented in the outcomes (7). Indeed, such adverse effects might be captured mainly by outsider perspectives, e.g., by stakeholders and hospitals without FIT64b models, which were not included in the study. However, since all stakeholders have also named several barriers to the implementation as well as the problematic effects of FIT64b models, we believe that we can confidently exclude the presence of such bias and that we have presented a rather balanced pictured of stakeholders' experiences.

The overall presentation of the SU and carers' experiences is very condensed within the described categories. For instance, we did not differentiate between short-, intermediate- and long-term outcomes of FIT64b models. Besides, SU were not considered as Input- and Throughput-factors in the "applied" Throughput-Model. This would have been of crucial importance, as the legal framework of FIT64b explicitly demands to strengthen patient orientation. In fact, our central concern in this study was to investigate the implementation process and basic change mechanisms of the care model mostly from a staff perspective. In the ongoing follow-up study "PsychCare" (2017 - 2020) these critical points are addressed, by using a co-productive methodology (45). For this purpose, so-called EEG ("experiential expert generated")-PREMS are currently being developed. These in

turn aim at improving the ecological validity of the logical diagram and its inherent change mechanisms from the SU' perspective.

CONCLUSIONS

The change from a daily- and performance-based to a lump-sum hospital payment across all settings (GTB) can be regarded as a key driver for the further development of psychiatric inpatient services toward a more flexible, integrative, ambulatory, and region-adapted treatment.

Besides, remuneration *via* an annual lump-sum eliminates the economic constraint that leads hospitals to fully occupy resource-intensive inpatient treatment places. In return, the incentive to act in a preventive and long-term resource-saving manner allows for low-threshold, outpatient and outreach services to be set up.

These changes in hospital financing and service provision lead to complex impacts on the stakeholders, which may not solely be captured by existing clinical outcomes. Key impacts of this care model are the improvement of need-adaptedness, relational continuity, and everyday-life orientation of treatment.

DATA AVAILABILITY STATEMENT

The datasets underlying the current study are not publicly available due to the used data protection declaration and the nature of qualitative interviews where individual participants could be possibly identified. Parts of the dataset are available from the research group on reasonable request.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by Ethics Committee of Medical Chamber Brandenburg, Cottbus, Germany [2016, No. S 7 (a)]. The patients/participants provided their written informed consent to participate in this study.

AUTHOR CONTRIBUTIONS

JS wrote the first draft of the manuscript. JS, LG, SP, and MH modified successive drafts. JS and SP were mainly responsible for development of the logical diagram. SP and MH contributed to the study design. All authors contributed to and have approved the final manuscript.

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The steering committee was in control of the study's budget. It supervised the development of the study design, but there was no influence on the collection, interpretation or representation of data.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2020. 00426/full#supplementary-material

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Conflict of Interest: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Implementation of a Global Treatment Budget in Psychiatric Departments in Germany—Results and Critical Factors for Success From the Staff Perspective

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Background: Despite evidence from other countries for its effectiveness, flexible and integrative psychiatric treatment (FIT) is not part of the German standard healthcare system. Since 2013, German legislative reform has enabled a test implementation of FIT based on a global treatment budget. Because the budget is not restricted to any particular activity, this legislation opens the possibility of enhancing linkages between inpatient-, outpatient- and day-patient treatment structures. As staff involvement is a relevant component in successful implementation, we aimed in this study to judge the degree of FIT implementation based on staff members' experiences and evaluations of FIT.

Method: Within an exploratory study design, we administered a standardized written survey to rate experiences and evaluations of physicians, psychologists, and nurses in the first 13 FIT projects between October 2016 and February 2017. The sample consisted of 352 nurses, 127 physicians, 84 psychologists, and 132 special therapists. We identified critical factors for successful implementation from the staff perspective by logistic regression analysis.

Results: Staff evaluations of the degree of FIT implementation were generally favorable, although some staff reported no experiences with one or several FIT-specific components. We found considerable differences in the assessments between the

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occupational groups. The only common factor for successful FIT implementation shared by physicians, psychologists, and nurses was the opportunity to join training programs on the objectives of FIT. Other critical factors for successful implementation were work conditions, the number of nurses/special therapists per physician/psychologist, and project duration. These factors together explained 49% of the variance of physician/psychologist evaluations and 34% for nurse evaluations. Individual staff members' characteristics were less important than structural- or FIT characteristics as explanatory factors for the degree of FIT implementation.

Implications: Results point to the importance of new forms of multi-professional cooperation, training programs, improvement of work conditions, and guidance of the implementation process by systematic Change Management for future implementations of FIT. Our exploratory findings require further validation to guide practical improvements in FIT implementation. Longitudinal observations and a multilevel analysis should yield a better understanding of the relevant variables from different organization levels and their possible interactions.

Keywords: flexible and integrative psychiatric treatment models, implementation, global treatment budget, mental health funding, personal services, cross-sectoral

INTRODUCTION

Despite good evidence for its effectiveness, internationally well-established community-based flexible and integrative psychiatric treatment (henceforth abbreviated as FIT) is not implemented in the standard German healthcare system (1–5). Instead, inpatient treatment based on per diem and performance-oriented payment approaches remains the major healthcare sector in Germany. This state of affairs may not entirely satisfy the requirements of needs-oriented and patient-centered care and may lead to overor under-utilization of healthcare services, or to other forms of misdirected use (6–10).

Since the year 2003, only single psychiatric departments in Germany have negotiated individual contracts for FIT with health insurance companies based on a "regional budget", otherwise known variously as "capitation model", "capitated payment system", "mental health capitation model", or "capitated model for psychiatric care". A nationwide implementation of FIT was enabled for the first time in Germany by a legislative reform in 2013 (§ 64b German Social Code Book V). This law allows for the test implementation of FIT in the special case of the treatment of patients suffering from psychiatric conditions (11). Scientific evaluations of the initial FIT projects have been encouraging for the further development of FIT projects (12–14).

FIT projects are based on a global treatment budget (henceforth abbreviated as GTB), which is an annually allocated and project-based fixed budget to cover all forms of treatment for a defined patient population. The GTB can be described as occupying a middle ground between block contracts and capitation payments. Block contracts have financing based on a fixed lump sum, which is roughly determined by precedents such as the historical expenditures for a particular service, but can be adjusted according to patient needs (15). The lump sum is

set irrespective of the number of patients treated or the amount of therapeutic engagement that is undertaken. Capitation payment involves payment of an annual lump sum for a given number of patients in the target population, irrespective of how many services the patients may receive (16–19). While capitation payment entails uniform remuneration per treated patient (bottom-up computation), GTB is based upon case numbers of the years prior to the contract (top-down computation). In practice, an initial normative or empirical calculation of remuneration per capita is multiplied by the number of such patients treated in the fiscal year. In its original conception, a bundled or rather episodic payment approach serves for FIT financing. Under this approach, a single annual payment is made for a package of services, which is calculated from the expected costs for the clinically defined care episodes (20).

An important aim of FIT is to redirect the focus of health care on individual patient needs and regional requirements, thus diverging from traditional provider-driven and mainly inpatient treatment structures (17, 21, 22). Because its budget is not restricted to any particular activity undertaken, the advent of FIT should foster cross-sectoral care by enhancing linkages among outpatient-, inpatient-, and day-patient treatment structures. Based on outcome research such as that reported in the present study, the German government shall decide by 2024 if FIT should become a standard part of the national healthcare system.

Initial research results, consisting of data from clinical account databases, cost analysis, patient- and individual staff-related findings are already available for the first FIT projects tested in Germany (21, 23, 24). However, available findings do not suffice to measure the degree of implementation for FIT with due consideration of their character as personal services. For such services, the outcome quality resides primarily in the quality

of interaction between the involved parties. In the case of clinical psychiatry, outcome quality reflects the interactions between patients and the treatment staff, who implicitly and explicitly communicate their attitudes towards (changed) work specifications (25-27). Barriers or conversely facilitators for FIT implementation may arise at various levels of healthcare delivery (28). In the case of personal services, it is the staff attitude towards structural and organizational changes that constitutes a critical factor for successful implementation (29-34). A key requirement for successful implementation is the extent to which staff are informed in advance of FIT-related structural and procedural changes, and are kept up to data about the experience gained upon adopting new measures in the occupational routine. However, merely experiencing these changes is not sufficient for successful implementation, which substantially depends on the care providers' evaluation of the modifications, including an integration into professional attitudes and daily work procedures. Ideally, health care providers should consider themselves as agents of change, rather than as passive recipients of evolving workplace specifications (25, 26, 29, 32, 33, 35). Failure of implementation often occurs when there is tacit opposition before even starting the process of change, resulting in an inability of the organization to "unfreeze" and adopt a stance of readiness for change (29, 33). Therefore, staff involvement is a highly relevant factor in evaluating the processes that lead to successful implementation.

This paper is part of the multi-center and mixed-methods exploratory study 'EvaMod64b', which aims to describe the multifaceted effects of the first Germany-wide FIT projects on patients, informal caregivers, and staff in relation to the degree of implementation of FIT projects (23, 24, 36). We now report results of our standardized written survey of evaluations by physicians, psychologists, and nurses on their experience with initiating FIT-related structures and procedures in the setting of psychiatric departments across Germany. We posed the following five questions to assess the degree of FIT implementation from the staff perspective: (1) To what extent are staff informed and experienced with FIT-related structures and procedures? (2) Does the degree of staff experience with FIT relate to the project duration? (3) How are characteristics of FIT evaluated by staff? (4) Which individual, organizational, and structural characteristics correspond best with the staff evaluations? (5) What are the critical factors for successful FIT implementation from the staff perspective?

MATERIALS AND METHODS

Setting and Sampling

The study was approved by the Ethics Committee Brandenburg [2016, No. S 7 (a)], thus adhering to the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The staff survey was approved by the respective institutional work councils. Potential participants received a verbal project-description, were informed about the voluntary nature of their participation, and were guaranteed anonymity.

In 2015, all 11 FIT projects established in 15 psychiatry departments in nine different German cities and regions were invited to join the study. Among these, leaders of nine projects from 13 departments agreed to participate (ten adult psychiatry and three child and adolescent psychiatry departments). Of the 13 departments, one withdrew from the study for organizational reasons. We inquired about sociodemographic, professional, and structural characteristics of the workplaces (as illustrated in point 2.2). The start dates of FIT extended from January 2013 to January 2016. Eight departments had established FIT for more than two years and the remaining four departments for two years or less at the time of data collection. Seven departments had a history of FIT in the form of individually negotiated contracts with health insurance companies, which were either according to GTB regulations or those of integrated care programs. The examined departments were either public (seven departments) or non-profit (five departments), providing care for regional populations ranging from 85,000 to 425,000 people. Eight departments were under contract with all national insurance companies. In the four departments having contracts with only one or two insurers, not all patients received FIT.

We administered the standardized written survey (as illustrated in point 2.2) of physicians, psychologists, nurses, and special therapists (e.g. occupational therapists, physiotherapists and music therapists) between October 2016 and February 2017. Only staff working in settings with partial or complete FIT implementation were interviewed. The sample consisted of 352 nurses, 127 physicians, 84 psychologists, and 132 special therapists (Table 1). Because of the considerable heterogeneity of special therapists' professional backgrounds and fields of activities, we confined our analysis to data provided by physicians, psychologists, and nurses. The participants were of mean age of 41 years and had on average 12 years of work experience in psychiatry. The majority of participants was female (73%) and worked full time (62%) in general psychiatry (40%). While physicians (75%) and psychologists (61%) mainly worked in the outpatient setting, nurses (77%) mainly worked in the inpatient treatment setting. The mean response rates by institution ranged between 31-88% for physicians/psychologists and 14-87% for nurses.

Measuring Staff Experiences and Evaluations of FIT-Specific Components and Work Conditions

We administered a questionnaire consisting of three parts: (1) sociodemographic, professional, and structural characteristics of staff and workplaces (29 items for physicians/psychologists, 34 items for nurses), (2) specific components of FIT (28 items), (3) work conditions (28 items for physicians/psychologists, 32 items for nurses). Part 1 inquired about sociodemographic factors such as age and gender, along with professional characteristics. These included noting if staff were serving full-time versus part-time, vocational training, years of professional engagement in psychiatry, and current position. Part 1 also covered structural aspects of the workplaces such as the treatment setting and number of colleagues. The questionnaire, which consisted of 94

TABLE 1 | Sociodemographic and professional characteristics of staff.

Characteristic	Physicians ($n = 127$)	Psychologists (n = 84)	Nurses (n = 352)
Age and Gender ^A			
Age (years, ± SD) Female Male	42.5 (± 10.6) (N = 123) 52.8%* (N = 67) 44.9%* (N = 57)	35.9 (± 11.5) (N = 83) 92.9%* (N = 78) 6%* (N = 5)	43.3 (± 11.9) (N = 290) 72.6% (N = 228) 27.4% (N = 86)
Experience ^A			
Work experience in psychiatry (years) (\pm SD) Length of employment in current institution (years) (\pm SD)	11.5 (± 9.6) (<i>N</i> = 122) 7.5 (± 6.9) (<i>N</i> = 113)	7.3 (± 8.2) (N = 82) 5.3 (± 6.3) (N = 76)	15.9 (± 9.9) (N = 287) 14.2 (± 9.3) (N = 273)
Working hours ^A			
Serving full-time (100%) Serving part-time (< 100%)	78.7%* (N = 100) 19.7%* (N = 25)	39.3% (N = 33) 60.7% (N = 51)	67%* (N = 217) 33%* (N = 107)
Position ^A			
Assistant physician	48.9% (N = 62)	n/a	n/a
Medical specialist without leading position Senior physician	15.7% (<i>N</i> = 20) 30.7% (<i>n</i> = 39)	n/a n/a	n/a n/a
Chief physician Psychologists	4.7% (n = 6) n/a	n/a 94% (n = 79)	n/a n/a
Leading psychologist	n/a	6% (n = 5)	n/a
Supervising nurse	n/a	n/a	18.2% (n = 59)
Nurse without leading position	n/a	n/a	81.8% (n = 266)
Education of nurses ^A (several answers possible)			
Nurse (3 years trained)	n/a	n/a	84.3% (n = 296)
Nursing assistant (1 year trained)	n/a	n/a	0.6% (n = 2)
Degree (Bachelor, Master)	n/a	n/a	2.8% (n = 10)
Specially trained psychiatric nurse (3 years trained + 2 years special training)	n/a	n/a	15.3% (n = 54)
Treatment setting ^A (several answers possible)			
Inpatient treatment setting	64.6% (n = 82)	46.4% (n = 39)	76.7% (n = 270)
Part-time inpatient setting	52% (n = 66)	57.1% (n = 48)	29.8% (n = 105)
Outpatient	74.8% (n = 95)	60.7% (n = 51)	30.1% (n = 106)
Others	11.8% (<i>n</i> = 15)	9.5% (n = 8)	1.7% (n = 6)
Current field of activity ^A			
General psychiatry	51.2% (n = 65)	$31\%^* (n = 26)$	37%* (n = 120)
Addiction medicine	10.2% (n = 13)	$8.3\%^* (n = 7)$	$12.3\%^* (n = 40)$
Psychosomatic medicine	7.1% (n = 9)	21.4%* (n = 18)	13.4%* (n = 43)
Gerontological psychiatry	3.9% (n = 5)	$9.5\%^* (n = 8)$	$6.5\%^* (n = 21)$
Child and adolescent psychiatry	12.6% (n = 16)	$10.7\%^* (n = 9)$	$15.4\%^* (n = 50)$
Mixed fields and others	15% (n = 19)	$17.8\%^* (n = 15)$	15.4%* ($n = 50$)

^AReference category; n/a = not applicable; * difference to 100% = missing values; SD = standard deviation.

items for nurses and 85 for physicians/psychologists, was administered in a pencil and paper format requiring 15-20 minutes for completion. Other core elements of our study encompassed by parts 2 and 3 are presented in more detail below.

FIT-Specific Components

To operationalize the staff perspective as a measure of the degree of FIT implementation, we defined two statistical metrics. These were based on the distinction between staff members' experiences and evaluations of FIT-related structures and procedures. The first of these metrics, 'experiences' (henceforth abbreviated as EX), is an index of whether staff members were informed about FIT-related structural and procedural changes and to what extent they experienced these changes in their occupational routine. The second metric, 'evaluations' (henceforth abbreviated as EV), is an index of attitudes towards and identification with the changes that were experienced.

The FIT projects differed with respect to factors such as project duration, size of catchment area, urban/rural area, treatment structures, and procedures. To accommodate this heterogeneity, we defined a set of 11 operationalized FITspecific components in a pilot stage of 'EvaMod64b', while following the Grounded Theory Methodology (23, 24, 36). After defining these components, we developed a 28-item questionnaire ('Characteristics, Structures and Procedures of Model Projects'), which operationalized these components to measure EX and EV (Table 2). The specific component 'accessibility of services', meaning the geographical and team accessibility, was not included in the questionnaire because this component related only to patients. We integrated two additional items, both referring to 'attitude change', which had not been defined in the initial component set, but emerged at a later stage of the study 'EvaMod64b'.

We posed the following key question to quantify EX and EV of FIT-specific components from the staff perspective, each

TABLE 2 | Definition, main and subordinate categories of FIT-specific components for the questionnaire 'Characteristics, Structures and Procedures of Model Projects'.

FIT-specific component and definition of component

Shifting in- to outpatient setting

Shift of treatment from inpatient- towards day-patient and/or outpatient treatment setting

Flexible care management across settings

Unproblematic shift of treatment setting (outpatient, day-patient, inpatient) (prompt, little bureaucracy)

Continuity of treatment team

Implementation of team- and individual-related continuity

Multi-professional cooperation

Intense multi-professional cooperation

Therapeutic group sessions across all settings

Therapeutic groups with members from all treatment settings (outpatient, day-patient, inpatient)

Outreach home care

Multi-professional treatment at home ≥ 1 week

Involvement of informal caregivers

Informal caregivers as therapeutic tool

Accessibility of services Geographical accessibility and accessibility of teams

Sovereign steering of services Freedom of therapeutic decisions

Cooperation across sectors

Cooperation with ambulant care systems

Expansion of professional expertise

Professionalization of staff

[†]Attitude change

Change of attitude due to implementation of FIT

Main and subordinate categories in questionnaire

*Shifting of treatment units from inpatient- towards day-patient- and/or outpatient treatment setting Systematic range of day-patient treatment

*Flexible transition from one to another setting Shifting wards to treatment focuses

*Continuity of treatment team across settings

Continuity of treatment across day-patient and inpatient treatment

*Systematic multi-professional cooperation

Obligatory multi-professional meetings

Networking of visiting outpatient service and inpatient treatment team

*Therapeutic group sessions across all settings

Development of patient- and staff groups across wards/functional areas

Networks for patients and integration in groups across all settings

*Systematic outreach home care offer (multi-professional, visiting, ≥ 1 week)

Systematic offer for home visits

Intensification of cooperation with residential homes

*Systematic involvement of informal caregivers

Inapplicable for staff, relevant only for patients

*Greater scope of action (e.g. leave of absence for patients; weekend holiday)

Individualized therapy plans take the place of standardized rules

Reduction of end of treatments through more possibility of differentiation, offers and compromises Flexibility of treatment procedure [e.g. certain treatment offers without prior approval of German medical service of healthcare insurance companies (MDK)] with larger margins for patients

*Management of treatment across sectors

Quality circles across treatment sectors

Development of networking groups with independent sponsors

*Increase of independent work

Specific training programs to the objectives of the model projects

Dissolving boarders between professions and teamwork is getting more important

Intensive patient involvement in therapy through informed consent

Closeness to the daily routine of patients and informal caregivers plays a key role in the treatment

*Main category for one FIT-specific component, † Additional category originated from a later stage of the study, not belonging to the initial FIT-specific components.

according to a one-answer scale with two subsections: "How do you rate the impact of structures/procedures for the treatment/ care for patients with mental illness in your hospital such as are already partially realized/enabled by FIT on the outcomes of your occupational routine in the past months?" In the first part, permitted responses about EX were "nonexistent" and "present, but not yet assessable". In the second part, permitted staff members responses for each item about EV were "present and assessable and my opinion of it is (...)" "very positive", "rather positive", "partly", "rather negative", and "very negative".

Work Conditions

Participants were asked to rate their present work conditions regarding supervision and hierarchy, conflict resolution ability of the team, work conditions on the ward/functional area, cooperation among occupational groups, requirements of patients, and opportunities for making joint decisions. Therefore, we adopted 23 questions for physicians/psychologists and 27 for nurses and special therapists from the German 'Questionnaire on Work Situation for Doctors' (FAÄ) (37) and the German 'Questionnaire for Nurses in Psychiatry' (FAPP) (38, 39), as well as five questions from the study "Registered Nurses Forecast" (RN4CAST) (40). We

modified the 6-point scale of the FAÄ and the FAPP, which was initially scored as 3 ("rather good") -2-1-1-2-3 ("rather poor") (2-1-1-2 were not precisely defined in the original version) to a 1-2-3-4-5-6 scale of descending quality. Here, scores ranged from 1, defined as "very good" or some comparable statement such as "very often", to 6, which was "very poor" or a comparable statement such as "occasionally".

The comprehensiveness of the questionnaire was reviewed by project members trained in empirical social research and with prior experience within the field of FIT, and by physicians, psychologists, nurses, and other professionals from every hierarchical level of four FIT departments. Subsequently, for the 28 item questionnaire ('Characteristics, Structures and Procedures of Model Projects'), each specific component was defined by one main and one or more subordinate categories (**Table 2**).

Data Analysis

The data analysis of EX and EV covered the ten main categories of the 28-item questionnaire 'Characteristics, Structures and Procedures of Model Projects'. The two items noted above referring to 'attitude change' were excluded from the analysis

because they were not among the initial FIT-specific components. In addition, the item 'specific training programs to the objective of the model project' (henceforth abbreviated as 'training programs'), initially assigned to a subordinate category of the specific component 'expansion of professional expertise' (**Table 2**), was integrated into the analysis, as noted below.

Individual staff members' ratings of organizational and structural characteristics of FIT departments as well as EX and EV were assessed *via* descriptive statistics. Participating departments were compared using structural data such as project duration and history of FIT in the form of individually negotiated contracts with insurance companies, extent of cooperation with health insurance companies, departments' sponsorship, and catchment size. Categorical data were tested using the χ^2 - test or Fisher's exact test in case of small cell counts.

EX was calculated descriptively *via* the three responses 1 = "nonexistent", 2 = "present, but not yet assessable", and 3 = "present and assessable". To calculate the relation between EX and the dichotomized variable 'project duration' (dichotomized as short $= \le 2$ years versus long = > 2 years), a Chi-square test was performed.

EV was calculated only in the event that EX was rated to be "present and assessable". EV scores then ranged from 1 (low/negative evaluation of implementation) to a maximum of 5 (high/positive evaluation).

The correlations between EV and the variables 'project duration' (dichotomized as above), 'training programs' (dichotomized as "rather positive", "very positive" versus "very negative", "negative", "partly"), as well as individual staff members' judgement of organizational and structural characteristics of FIT departments, were analyzed *via* Spearman correlation.

The five research questions posed under point 1 were tested in an exploratory manner with α of 5% with no use of alpha-adaption. Test results with $p < \alpha$ (5%) were here deemed significant.

For the binary logistic regression, EV was dichotomized to 1 = "very negative", "negative", "partly", and 2 = "rather positive", "very positive". For physicians/psychologists, logistic regression was performed with EV as the dependent variable and the independent variables 'age' (> versus ≤ mean), 'duration of employment in psychiatry' (> versus ≤ mean), 'number of nurses/special therapists per physician/psychologist' (> versus ≤ median 3.3), 'project duration' (dichotomized as above), 'training programs' (dichotomized as above), and 'sum of positively rated work conditions' (≥ versus < 50% of work conditions positively rated). We defined the number of nurses/special therapists per physician/psychologist as the number of nurses/special therapists per primary physician or psychologist, all considered as one group. For nurses, the regression was calculated with EV as the dependent variable and the independent variables 'training programs' (dichotomized as above), 'sum of positively rated work conditions' (≥ versus < 50% of work conditions positively rated), 'project duration' (dichotomized as above), and 'supervisor for other nurses' (being supervisor for other nurses versus no status as supervisor). For both groups, we made the binary logistic regression based on the results of the exploratory Spearman correlation. Statistical results were computed by SPSS 15 and 22.

RESULTS

For the questionnaire 'Characteristics, Structures and Procedures of Model Projects', Cronbach's α for physicians'/psychologists' questions was 0.86 for EX and 0.88 for EV, which are both regarded as good (= > 0.8) according to the definition of Cronbach (41). For nurses' questions, Cronbach's α was excellent (= > 0.9), with 0.99 for EX and 0.92 for EV (41). After modification of the 6-point scale of the 'Questionnaire on Work Situation for Doctors' (FAÄ) and the corresponding questionnaire for nurses (FAPP), as mentioned in point 2.2, Cronbach's α remained good (> 0.8) for physicians'/psychologists' questions and likewise for nurses (0.84 for EX and 0.88 for EV).

In the following sections, we present EX, EV, and critical factors for success in the evaluations of FIT from the staff perspective.

Experiences With FIT-Specific Components (EX)

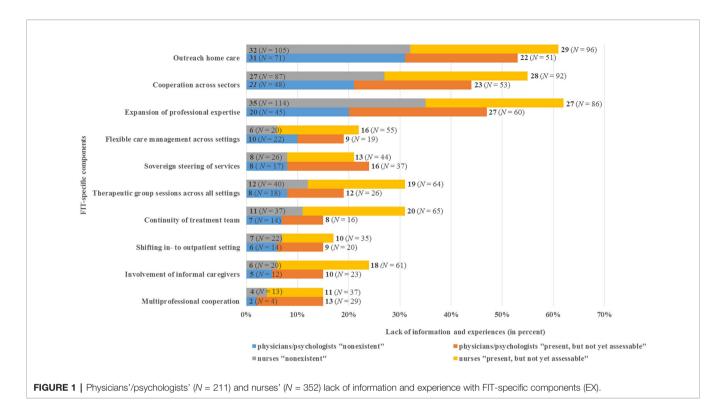
EX was higher for nurses compared to physicians/psychologists with respect to eight of the ten FIT-specific components, indicating that nurses were less informed and experienced with FIT-specific components at the time of data collection (**Figure 1**). Comparing the answers by physicians/psychologists with those of nurses, the largest difference related to the component 'expansion of professional expertise' (20% of physicians/psychologists vs. 35% of nurses stated "nonexistent"). Remarkably, 36% of physicians/psychologists and 27% of nurses stated that no training programs on objectives of FIT existed in their departments. Additionally, 22% of the physicians/psychologists and 28% of the nurses stated that training programs were present, but were not assessable to them.

As shown by the EX results, up to 31% of physicians/psychologists and 35% of nurses were not experienced with at least one of the FIT-specific components (**Figure 1**). For instance, 31% of physicians/psychologists and 32% of nurses reported no experience with the component 'outreach home care'. In addition, 21% of physicians/psychologists and 27% of nurses stated that their department did not cooperate with other institutions across various health service sectors. The maximum values of EX were found for the component 'multi-professional cooperation', with 2% of physicians/psychologists and 4% of nurses assessing this component as "nonexistent".

While for nurses there was no significant relation between EX and the project duration (x^2 (2) = 3.323, p = 0.190, n = 304), the Chi-square test was significant for physicians/psychologists (x^2 (2) = 9.948, p = 0.007, Cramer's V = 0.235, n = 180) (42). This indicates that nurses had less experience than did physicians/psychologists with FIT-specific components, even after two years of project duration.

Evaluations of FIT-Specific Components (EV)

The mean value for EV, covering all ten FIT-specific components, was 4.4 of a maximum of 5 for physicians/psychologists and 3.9/5 for nurses (**Figure 2**). These values indicate rather positive



evaluations of FIT by the surveyed nurses and to an even greater extent by physicians/psychologists.

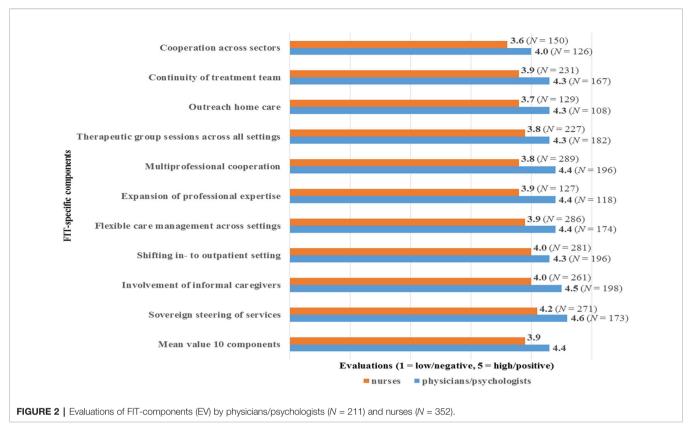
The highest mean values of EV were found for the component 'sovereign steering of services' (4.6 for physicians/psychologists, 4.2 for nurses), and the lowest values for the component 'cooperation across sectors' (4.0 for physicians/psychologists, 3.6 for nurses). Overall, nurses' EV scores were at least 0.3 points lower compared to these of physicians/psychologists. The comparison showed maximum differences between the EV of the occupational groups regarding the components 'outreach home care' and 'multiprofessional cooperation' (both with a difference of 0.6). The least difference between physicians/psychologists and nurses occurred in relation to the component 'shifting in- to outpatient setting' with a difference of 0.3.

Bivariate analysis of the EV and individual, organizational, and structural characteristics for physicians/psychologists showed significant positive correlations between EV and higher age (p=0.017), longer duration of employment in psychiatry (p=0.015), and the higher number of nurses/special therapists per physician/psychologist (p=0.006) (**Table 3**). For nurses, bivariate analysis showed a significant negative correlation between EV and the variable 'supervisor for other nurses' (p=0.022). For both occupational groups, a positively rated opportunity to join training programs (both groups p<0.001), a higher sum of positively rated work conditions (physicians/psychologists p=0.006, nurses p<0.001), and longer project duration (physicians/psychologists p=0.012, nurses p=0.016) correlated significantly with a higher value of EV.

Critical Factors for Success

The model for physicians/psychologists, as introduced in point 2.3, was significant for EV ($x^2(6) = 24.477$, p < 0.001, n = 68), but not for every coefficient within the above exploratory bivariate analysis (Table 4). The chance for a positive evaluation (EV) of the FIT-specific components for physicians/psychologists increased 16.5-fold when the item 'training programs' was positively evaluated (p = 0.008), 13.2-fold for a higher number of nurses/special therapists per physician/psychologist (p = 0.013), and 10.4-fold for a project duration exceeding two years (p = 0.036). Inclusion of the coefficients 'age', 'sum of positively rated work conditions', and 'duration of employment in psychiatry' did not contribute significantly to the prediction of the EV outcome. While showing no significant effect in the regression analysis, the coefficient 'age' was negatively associated with EV. Thus, 49% of the variance of EV could be explained by only three significant independent variables, corresponding to a strong effect according to Cohen (42).

The model for nurses was significant for EV ($x^2(4) = 32.605$, p < 0.001, n = 112), but not for each coefficient selected on the basis of the exploratory bivariate analysis described above (**Table 5**). For nurses, the chance for a positive evaluation (EV) of the FIT-specific components increased 5.1-fold when a higher sum of work conditions was rated positively (p = 0.001) and 4.9-fold when 'training programs' was positively evaluated (p < 0.001). Inclusion of the coefficients 'supervisor for other nurses' and 'project duration' did not contribute significantly to the prediction of the EV outcome, even though both coefficients showed a negative association with EV. Thus, 34% of the variance of EV could be explained by the three



significant independent variables, corresponding to a strong effect according to Cohen (42).

DISCUSSION

Degree of FIT Implementation

Overall, the experiences of FIT were evaluated rather positively by nurses and even more so by physicians and psychologists. Implementation, measured by scores in staff evaluations, was generally most advanced in the FIT-specific component 'sovereign steering of services' and least successfully in 'cooperation across sectors'. The importance of both of these aspects is a familiar result from other hospital workplace research. Autonomy in clinical decision processes is considered one of the most important components of work satisfaction (43-45). In contrast, a perceived lack of autonomy may contribute to work dissatisfaction, higher rates of staff turnover, lower effectiveness in clinical settings, and higher healthcare costs (45, 46). The occurrence of inadequate cooperation across sectors is a well-known deficiency of the German healthcare system. The need to correct this lack of cooperation was a key motivation for the legislative reform allowing FIT implementation based on a GTB (11, 23, 47).

While we registered a generally favorable assessment of the degree of FIT implementation according to staff evaluations, a significant proportion of the staff nonetheless reported having had no experience with one or more FIT-specific components. 'Outreach home care' and 'cooperation across sectors' were deemed the least advanced of the implemented components

according to staff experiences. We note that several departments had not implemented the component of 'outreach home care' at the time of data collection. As suggested by the scant experience and relatively poor evaluations of 'cooperation across sectors', this item emerges as an FIT-specific component particularly in need of efforts for improved implementation.

Regarding the interpretation of EV, we note the importance of considering that changes in the workplace associated with FIT (for example, the delegation of more responsibility, demands for professional development, and greater inter-professional cooperation) were not to the liking of every employee. We suppose that some employees were averse to, or felt overburdened by these changes in routine.

As discussed in the section below, present results indicate that individual characteristics of staff (e.g. age, qualification) played a less important role concerning the degree of implementation than did characteristics of FIT (e.g. project duration) and structural aspects of FIT departments (e.g. the sum of positively rated work conditions).

Factors for Success in FIT Implementation

Regression analysis identified four factors for success, namely (1) positive evaluation of the opportunity to join training programs about the objectives of FIT, (2) project duration, (3) work conditions, and (4) the number of nurses/special therapists per physician/psychologist. The only factor for success in FIT implementation from the perspectives both of physicians/psychologists and of nurses was the positive evaluation of the opportunity to join training programs about the objectives of

TABLE 3 | Results of the bivariate Spearman analysis for individual, organizational, structural characteristics, and the evaluations (EV) of physicians/psychologists and nurses.

Characteristics	Physicians/ psychologists (n = 211)	Nurses (n = 352)	
Individual characteristics ^A			
Age (> versus ≤ mean) Gender (male versus female) Qualification (not certified versus certified)	r = 0.17* (p = 0.017) r = -0.12 (p = 0.10) n/a	r = 0.07 (p = 0.29) r = 0.06 (p = 0.32) r = -0.04 (p = 0.48)	
Training duration (other versus 1-year training (nurses)	n/a	$r = -0.03 \ (p = 0.62)$	
Professional status as a nurse: being supervisor for other nurses versus no status as supervisor	n/a	$r = -0.13^* (p = 0.022)$	
Professional status as physician (assistant physician versus specialist without leadership position, senior physician, chief physician)	r = -0.00 (p = 0.96)	n/a	
Duration of employment in psychiatry (> versus ≤ mean)	$r = 0.17^* (p = 0.015)$	$r = 0.03 \ (p = 0.58)$	
Duration of employment in current department (> versus < mean)	$r = 0.13 \ (p = 0.07)$	$r = 0.01 \ (p = 0.88)$	
Full-time (100%) versus part- time (< 100%) employment	$r = -0.05 \ (p = 0.45)$	$r = -0.03 \ (p = 0.67)$	
Organizational characteristic		,	
Number of nurses/special therapists per physician/ psychologist (> versus ≤ median 3.3)	$r = 0.18^{**} (p = 0.006)$	n/a	
Existence versus non- existence of a FIT-feedback system	$r = -0.03 \ (p = 0.66)$	$r = 0.02 \ (p = 0.78)$	
Opportunity to join specific training programs to the objective of the model project ("rather positive," "very positive" versus "very negative," "negative," "partly")	$r = 0.37^{***} (p < 0.001)$	$r = 0.04^{***} (p < 0.001)$	
Sum of positively rated work conditions from 23 (physicians/psychologists) or 27 (nurses) items (≥ versus < 50% of work conditions positively rated) Structural characteristics ^A	$r = 0.19^{**} (p = 0.006)$	r = 0.38*** (p < 0.001)	
Department's sponsorship (public versus non-profit, private)	$r = 0.00 \ (p = 0.97)$	$r = 0.08 \ (p = 0.16)$	
Project duration (> versus ≤ 2 years)	$r = 0.17^* (p = 0.012)$	$r = 0.13^* (p = 0.016)$	
Competitive versus no competitive situation to another hospital	$r = 0.12 \ (p = 0.11)$	r = 0.02 (p = 0.75)	

A Reference category; n/a, not applicable; *p < .05, **p < .01, ***p < .001; r =Spearman Rank correlation coefficient

FIT. The chance for a positive evaluation of FIT was increased 16.5-fold for physicians/psychologists and 4.9-fold for nurses by this variable. Given its reported importance for staff, it seems remarkable that 36% of physicians/psychologists and 27% of nurses stated that no training programs existed in their departments. This

TABLE 4 | Full binary logistic regression for evaluations (EV) of physicians/psychologists and selected independent variables (*N* = 68).

Variable	b (SE)	p	95% CI for Odds Ratio		
			Lower Bound	Odds Ratio	Upper Bound
Duration of employment in psychiatry (> versus ≤ mean)	0.19 (0.09)	0.053	0.99	1.21	1.46
Number of nurses/special therapists per physician/psychologist (> versus ≤ median 3.3)	2.57 (1.03)	0.013*	1.72	13.18	100.97
Project duration (> versus ≤ 2 years)	2.34 (1.12)	0.036*	1.15	10.41	93.58
Opportunity to join specific training programs to the objective of the model project ("rather positive", "very positive" versus "very negative", "negative", "partly")	2.80 (1.06)	0.008**	2.06	16.49	131.77
Sum of positively rated work conditions from 23 (physicians/psychologists) (> versus < 50% of work conditions positively rated)	0.74 (0.83)	0.376	0.40	2.09	10.77
Age (> versus ≤ mean)	-0.10 (0.06)	0.106	0.78	0.89	1.02

^{*}p < .05, **p < .01; Cl, confidence interval; b, regression coefficient; SE, standard error of regression coefficient.

TABLE 5 | Full binary logistic regression for evaluations (EV) of nurses and selected independent variables (*V* = 112).

Variable	b (SE)	p	95% CI for Odds Ratio		
			Lower Bound	Odds Ratio	Upper Bound
Project duration (> versus ≤ 2 years)	-0.16 (0.46)	0.731	0.34	0.85	2.12
Professional status as a nurse: being supervisor for other nurses versus no status as supervisor	-0.72 (0.53)	0.176	0.16	0.48	1.38
Opportunity to join specific training programs to the objective of the model project ("rather positive", "very positive" versus "very negative", "negative", "partly")	1.59 (0.45)	< 0.001***	2.03	4.90	11.83
Sum of positively rated work conditions from 27 (nurses) (≥ versus < 50% of work conditions positively rated)	1.63 (0.47)	0.001**	2.03	5.12	12.91

^{**}p < .01, ***p < .001; CI, confidence interval; b, regression coefficient; SE, standard error of regression coefficient.

discrepancy emphasizes that the return on investment for training programs should not be underestimated as a factor for better understanding, participation, and integration of planned modifications, thus positively influencing attitudes and procedures.

For physicians/psychologists, the second most critical factor for successful FIT implementation was a higher number of nurses/special therapists per physician/psychologist. We suppose that higher staffing with nurses/special therapists may relieve some organizational or other burden placed on physicians/psychologists, especially during the early phase of FIT implementation, when our prior research indicates an increased workload (23).

Project duration was the third critical factor for success from the perspective of physicians/psychologists. This finding illustrates that clinical staff need sufficient time to grow accustomed to the FITrelated changes and to undergo certain modifications of professional attitudes and daily work procedures. Especially during the departure phase, that is to say the first two years of FIT implementation, staff has to accommodate a drastic reduction of the number of beds and the adoption of new treatment concepts (23). In this early phase, it was sometimes necessary for staff to manage double routines, especially in those departments not under contract with all national health insurance companies (23). The finding that project duration is important for the degree of FIT implementation is also consistent with earlier results showing that a longer duration of Crisis Resolution Team, Assertive Outreach Team, or Community Mental Health Treatment predicted for fewer experiences of emotional exhaustion and depersonalization in response to procedural changes (48).

From the perspective of nurses, the work conditions were the most critical factor for successful FIT implementation. Consistent with this finding, a report by Aiken et al. (2011) drawing upon 25 years of research in several countries, including Germany, showed that work conditions had positive impacts on nurse and patient outcomes (49). The relevant aspects of so called 'work environment' were operationalized by Aiken et al. as adequate staffing resources, nurse management ability and leadership, nurse-physician relations, nurse participation in hospital affairs, and the presence of nursing foundations for quality of care (49). Hospitals with consistently superior work environments had distinct advantages as: lower burnout rates for nurses, higher likelihood that nurses would report that their patients were ready for discharge, and lower probability of having nurses who were dissatisfied with their job, or who deemed the quality of care on their wards to be only fair or poor (49). Furthermore, in the context of psychiatry, positive aspects of organizational behavior such as unit manager's skill at leadership, strong collegial nurse-physician relationships, and higher nursepatient staffing ratios have all been associated with lesser occurrence of nurse burnout as well as lower rates of adverse clinical events (50-52).

These factors for successful FIT implementation show differences between the physicians'/psychologists' and nurses' experiences and evaluations. The main differences are highlighted in the following section.

Differences Between Occupational Groups

Physicians and psychologists experienced FIT-related changes earlier in the implementation process and also more often than did nurses. Furthermore, nurses' evaluations were less positive in every FIT-specific component. As suggested by our finding of the importance of project duration, physicians/psychologists became more easily accustomed to FIT-related changes than did nurses after a project duration of two or more years. We also see a (though not significant) trend toward worse evaluations from

nurses with longer project duration and among nurses acting in a supervisorial role over other nurses. A sustained increase in workload, which is a plausible factor for additional stress for nurses during the implementation process, likely explains the greater importance of project duration as a factor for success perceived for physicians/psychologists. Since the experiences between the groups differed mainly for the component 'expansion of professional expertise' (which 20% of physicians/psychologists vs. 35% of nurses stated as "nonexistent"), we suppose that an unbalanced (re)distribution of tasks between the occupational groups during the implementation process may be a key reason for the differing ratings. Such a task redistribution was found by the study of Bartholomeyczik et al. (2008), where physicians seemingly passed on more tasks to nurses, while nurses were generally unable to reciprocate or engage other occupational groups (53). The degree of FIT implementation, as measured by EV, had the greatest difference between groups for the components 'outreach home care' and 'multi-professional cooperation'. On the other hand, 'shifting in- to outpatient setting' showed the least difference between the evaluations of the groups. As several FIT departments did not implement outreach home care at the time of data collection, these discrepant experiences may arise from the physicians/psychologists being more involved in the theoretical aspects of new developments than were nurses, such that they had a better opportunity to understand and identify with this component (54). In contrast to 'outreach home care', a shift of treatment units from inpatient- towards day-patient and/or outpatient treatment setting was evident as the main component in 'shifting in- to outpatient setting' at the very onset of FIT projects (23). This shows that staff members with different occupational backgrounds had comparably positive identification with this component.

Although multi-professional cooperation was the component most strongly experienced by staff, the high discrepancy between staff evaluations indicates that divergent and possibly conflicting viewpoints may occur at the interface of occupational groups, which could certainly present a barrier for successful FIT implementation. Consistent with this finding, other studies have reported a persistent failure to attain adequate multiprofessional cooperation (52, 55). A point of criticism in this regard is that a common understanding about objectives of patient care, extending beyond the simple label "patientcentered", is often lacking (56). For example, medical and nursing processes often undergo separate planning, without addressing their mutual impacts and conditions. Specifically, there can be insufficient agreement about treatment objectives, which is compounded by the separate documentation systems for physicians and nurses (56, 57). Moreover, multi-professional cooperation mainly rests on the self-organization of wards/ functional areas and such activities are typically regulated informally (55, 56).

Strengths and Limitations of the Study

This is the first study judging the degree of FIT implementation based on psychiatric staff members' experiences and evaluations of FIT in Germany. Therefore, the present results may inform about further adaptations necessary for improved FIT implementation on different organizational levels. Thus, results of the study may contribute to the development of national and international FIT projects.

According to our understanding, FIT is primarily a personal service. Therefore, we adopted a bottom-up strategy to measure the degree of implementation from the staff perspective, as indicated by the calculated values EX and EV. The strength of this strategy lies in its capacity to capture the perspective of those health workers who initiate and actively engage in treatment processes, or conversely those staff who (for whatever reason) present a barrier to implementation efforts. Therefore, gaining insight into the staff perspective plays a critical role for better understanding the factors underlying successful FIT implementation. Concurrent performance of staff surveys may also facilitate the organization's ability to "unfreeze" and therefore obtain greater flexibility in creating readiness for implementation.

We note that the present study design may be vulnerable to some selection bias. Some staff might have refused to participate in the study because they are not interested in the implementation of the new treatment model or do not agree with its aims and implications. We cannot exclude the possibility that staff who support the model might have been over-represented in the group of survey respondents. Certainly, self-reporting brings a well-known risk of information bias (58). Staff who support FIT might have given more positive answers, while those with reservations may feel pressured to participate, or even be fearful of consequences despite the guarantee of their anonymity. Moreover, the key question to quantify EX and EV was too long and therefore might have caused difficulty in understanding as well as withdrawal from filling in the questionnaires.

As the present study was exploratory in nature, our findings need further validation in prospective studies. Our cross-sectional design limits the making of causal inferences and we can therefore make no statements about the reproducibility of the results in other settings. The four factors for successful FIT implementation together explained 49% of the variance of EV for physicians/psychologists and 34% for nurses, corresponding to a strong effect in both cases. However, there must remain other relevant factors yet to be identified. We also concede that the study lacks the perspective of special therapists, who were excluded from data analysis because of the considerable heterogeneity of their professional backgrounds and fields of activities. This may have decreased the transferability of present findings to other contexts.

Practical Implications and Directions for the Future

Because attaining a high degree of implementation requires that a sufficient understanding of FIT-specific components 'reaches' or gets through to staff, it follows that closing the gap of experiences and evaluations between the occupational groups should be of high priority. Enabling this process would require a deeper integration of tasks as well as equal participation

opportunities for the different occupational groups, e.g. entailing new forms of cooperation and training programs.

In the following section, we present practical implications and directions for the future based on present findings.

New Forms of Multi-Professional Cooperation

As early as 2007, the German Advisory Council on the Assessment of Developments in the Health Care System noted that the distribution of tasks between occupational groups did not meet the demographic, structural, and innovation-related requirements of the healthcare system (47). To close the gap of experience and evaluation between the occupational groups, FIT departments may have an opportunity systematically to develop and test new forms of multi-professional cooperation and competencies for occupational groups. These efforts could be tailored to the recommendations of the Advisory Council and the stated aims of FIT, which are well compatible and mutually beneficial. The Council recommended that new forms of cooperation should not primarily derive from the interests of any single occupational group, but from patient-based future demands of the healthcare system. However, it would be overly simplistic merely to (re)distribute single tasks within a system. Such an approach would likely increase the existing disparities between occupational groups on different levels. For example, disparities in workload on a micro-level or disparities in accounting resources on meso- or macro-levels, without bringing a corresponding expansion of expertise, which is itself an FIT-specific aspiration. Therefore, we should raise the question of what precisely should be the professional profile for occupational groups in FIT. Another question is what tasks may properly be redistributed to focus best on meeting the demands of the health system and improving multiprofessional cooperation.

Training Programs

Another pathway to facilitate adoption of FIT may be to implement obligatory and ideally multi-professional training programs, as this emerged as the only common factor for successful implementation identified by both occupational groups in our study. While the diffusion of FIT-related information by implicit processes (for example, driven by hierarchical organizational structure or problematic power dynamics) resists short-term alteration, a strategy for dissemination of information about FIT might be implemented rapidly through training programs. This exposure could increase the experience of staff with FIT, which is an essential factor for attaining better understanding and identification with FIT-specific components.

Training programs may also give an opportunity for different occupational groups to consider FIT as a common project with matching of tasks according to defined and shared objectives of optimal patient care (47, 56). Although not an end in itself, multi-professional cooperation is a necessary precondition for attaining worthwhile interactions between all participants (17,

56). As other studies have shown, the implementation of a multiprofessional treatment philosophy is not always free of conflicts, but presupposes an enhanced willingness of staff to negotiate amongst each other towards achieving a common goal (53, 55).

Systematic Change Management

As mentioned above, we found that individual demographic characteristics of staff (e.g. age, qualification) played a less important role in explaining the degree of implementation than did structural- and particular characteristics of FIT. This aspect presents an additional argument for implementing workshops, training programs, and other internal and/or external training opportunities such as Change Management. Systematic Change Management programs can promote the modification of organizational behavior, structures and procedures, as well as professional attitudes. It takes time for individuals to assimilate new forms of work and to change work routines, which may have been established and reinforced for years. Especially in the departure phase during the first two years of FIT implementation, it is necessary to manage restraining forces such as double routines and the risk of increased workload. In addition to training programs, other measures as for example Change Management are necessary to avoid excessive workload, rejection of FIT-specific components, and inner emigration when managing change. Only then can changes become a durable and accepted feature of the daily routine. Although arising from a different clinical area, we note the exemplary results for programs to reduce catheter-associated urinary tract infections, which have demonstrated the success of measures to facilitate adaption of change. Examples for key factors for success were repeated training and other measures such as audit and feedback, provision of electronic applications as reminders (59– 62), as well as efforts to maintain and encourage positive changes, for example by a sustainability plan. Another exemplary case reported by Bartholomeyczik et al. (2008) suggests that forcing a clinical implementation without process-related restructuring may have positive/exonerative effects for one group (physicians in the Bartholomeyczik study), whereas others (nurses) may experience an increased burden without concomitant expansion of expertise (53).

Nurses Work Conditions

Facilitation of FIT implementation may benefit from attending to the factors that bring untoward structural strain especially for nurses during the implementation process. Personnel assessment and the tailored design of work conditions may affect not only the implementation of FIT, but also the outcomes for all stakeholders. For example, there is strong evidence for a significant association between lower patient-to-nurse ratios and lower patient mortality (63–65) and risk-adjusted mortality (66–69). Furthermore, nurse burnout and job dissatisfaction appeared to be barometers for patient satisfaction in those same hospitals (70). As mentioned above, psychiatry department organizational behavior is also associated with the level of adverse events (50, 51).

As we report above, nurses may tend to be less involved in the theoretical development of FIT and may therefore have less

opportunity than physicians/psychologists for active participation in the implementation process. Therefore, we see a need for more brings the voice of nurses into FIT-related decisions, aiming to facilitate the implementation process and enable better outcomes for patients and nurses alike (49).

Further Research

Our exploratory findings need further substantiation and development to improve the practical implementation of FIT. Longitudinal observations over greater time intervals are necessary to support causal inferences and to enable the drawing of firm conclusions about the generalizability of the present results. In could be useful to implement a multilevel analysis or structural equation modelling approach in our analysis, as this approach might impart a better understanding of the variables arising from different organizational levels and their possible interplay. As individual characteristics of staff such as age and qualification seem to be minor factors for explaining EV, it would be interesting to survey the relevance of personal traits for successful implementation. Future research on FIT implementation should differentiate single work conditions such as supervision and the presence of hierarchy or cooperation among occupational groups, as well as the workload, participation opportunities, and (re)distribution of tasks between the occupational groups.

DATA AVAILABILITY STATEMENT

The datasets underlying the current study are not publicly available due to the used data protection declaration. Parts of the datasets are available from the corresponding author on reasonable request.

ETHICS STATEMENT

The studies involving human participants were reviewed and approved by the Ethics Committee Brandenburg [2016, No. S 7 (a)], thus adhering to the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

AUTHOR CONTRIBUTIONS

SI wrote the first draft of the manuscript. SP and MH modified successive drafts. SI and BB developed the study design and were responsible for the statistical analysis and the interpretation of the data. All authors contributed to the article and approved the submitted version.

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The reviewer AB declared a shared affiliation, with no collaboration, with one of the authors, SI, to the handling editor at the time of review.

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<u>Lebenslauf</u>

Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht.

Komplette Publikationsliste

- **1. Indefrey S**, Braun B, von Peter S, Bechdolf A, Birker T, Duve A, Hardt O, Heiser P, Hojes K, Rehr B, Scherk H, Schulz-Du Bois AC, Wilms B, Heinze M. Implementation of a Global Treatment Budget in Psychiatric Departments in Germany–Results and Critical Factors for Success From the Staff Perspective. Frontiers Psychiatry, 2020; 11:610. DOI: 10.3389/fpsyt.2020.00610.
- **2.** Schwarz J, Galbusera L, Bechdolf A, Birker T, Deister A, Duve A, Heiser P, Hojes K, **Indefrey S**, Johne J, Rehr B, Rout S, Scherk H, Schulz-Du Bois A, Wilms B, Zedlick D, Zeipert M, Heinze M and von Peter S. Changes in German Mental Health Care by Implementing a Global Treatment Budget A Mixed-Method Process Evaluation Study. Frontiers Psychiatry, 2020; 11:426. DOI: 10.3389/fpsyt.2020.00426.
- **3.** Schwarz J, Zeipert M, Ignatyev Y, **Indefrey S**, Rehr B, Timm J, Heinze M, Von Peter S. Implementierungsstand und Erfahrungen der Stakeholder mit der Zuhause-Behandlung in psychiatrischen Modellvorhaben (nach §64b SGB V) Eine Mixed-Methods Studie. Psychotherapie, Psychosomatik, Medizinische Psychologie, 2020; 70(02):65-71. DOI: 10.1055/a-0942-2163.
- **4.** von Peter S, Ignatyev Y, Johne J, **Indefrey S**, Kankaya OA, Rehr B, Zeipert M, Bechdolf A, Birkner T, Deister A, Duve A, Rout S, Scherk H, Schulz-Dubois A, Wilms B, Zedlick D, Grollich P, Braun B, Timm J and Heinze M (2019) Evaluation of Flexible and Integrative Psychiatric Treatment Models in Germany—A Mixed-Method Patient and Staff-Oriented Exploratory Study. Front. Psychiatry 9:785. DOI: 10.3389/fpsyt.2018.00785.
- **5.** Ignatyev Y, Timm J, Heinze M, **Indefrey S**, von Peter S. Development and Preliminary Validation of the Scale for Evaluation of Psychiatric Integrative and Continuous Care—Patient's Version. Front. Psychiatry, 2017; 8:162. DOI: 10.3389/fpsyt.2017.00162.
- **6.** von Peter S, Ignatyev Y, **Indefrey S**, Johne J, Schwarz J, Timm J, Heinze M. Spezifische Merkmale zur Einstufung der Modellversorgung nach §64b SGB V. Nervenarzt 2017; 89(5): 559-564. DOI: 10.1007/s00115-017-0459-z.
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- **8.** Hasseler M, von der Heide M, **Indefrey S**. Resources for and barriers to effective diabetes care management experiences and perspectives of people with type 2 diabetes. Journal of Public Health, 2011; 19(1):65-71. DOI: 10.1007/s10389-010-0354-6.
- **9. Indefrey S**, Hasseler M, Behncke A, Heidl C, Kran H, Pichlmüller K, Schödel S, Strupeit S. Versorgungssituation auf dem Prüfstand: Wie erleben Frauen mit Brustkrebs ihre Versorgung? Senologie Zeitschrift für Mammadiagnostik und –therapie, 2011; 8-A93. DOI: 10.1055/s-0031-1278095. (Abstract).
- **10.** Heidl C, Behncke A, **Indefrey S**, Kran H, Pichlmüller K, Schödel S, Strupeit S, Hasseler M. Problematik Versorgungsforschung auf der Mikroebene. Senologie Zeitschrift für Mammadiagnostik und –therapie, 2011; 8 A74. DOI: 10.1055/s-0031-1278076. (Abstract).
- 11. Indefrey S, Hasseler M. Empowerment als theoretische Grundlage für ein berufsgruppenübergreifendes und wohnortnahes Diabetesmanagement. Pflege & Gesellschaft, 2010; 15(3):255-265.

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