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Evaluation of therapy support through a standardized nursing consultation for patients undergoing oral tumor therapy in gynecological oncology within the prospective CAMPA initiative

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ABSTRACT

Purpose: The increase of oral tumor therapies (OTT) poses new challenges in patient care. Within CAMPA (Care improvement for advanced or metastatic breast and ovarian cancer patients treated with PARP-inhibitors), additional nursing support for patients treated with PARP-inhibitors was developed.
Methods: Additional nursing support (1 year) was evaluated in breast and gynecooncological cancer patients at an academic and a non-academic outreach center. From 02/22 to 02/24, quality of life, contacts, adherence, documentation of drug intake, hospitalization, and adverse events were evaluated, using CANKADO-ePRO and validated questionnaires reviewed by the Ethics Committee of Medical Faculty, LMU Munich. Satisfaction with care was recorded from 03/23 to 02/24. Supporting materials and interprofessional checklists were explored.
Results: The collective ($n = 50$) included 41 patients with ovarian, 4 with fallopian tube and 5 with breast cancer. Adherence measured by continuous documentation of medication intake was high among patients (78.0%). Quality of life improved from 68.6% to 81.4%, strongly correlating with decreasing numbers of side effects ($p = 0.003$) (Spearman $|\rho| = 0.93$). Satisfaction with care was very high (4.97 out of 5 points). 94.6% agreed that nursing consultation was essential for therapy safety compared to the doctor's consultation alone ($p < 0.05$). The reduction in time and care effort was significant ($p < 0.05$), having its maximum within the first three months.
Conclusion: Standardized nursing consultation was highly appreciated with an important contribution to adherence and improvement in quality of life. Delegation of therapy management to nurses reduces time effort and increases their responsibility, improving interprofessional care at academic and non-academic institutions.
Trial registration: Clinical Trials Registry, LMU university hospital, Germany, Healthcare research project, number: 21–0848.

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1. Introduction

In recent years, the exponential increase of new anticancer compounds has broadened treatment options for metastatic breast cancer (MBC) and recurrent ovarian cancer (OC) and resulted in a significant improvement of life expectancy (Robson et al., 2019). Several new oral therapies are now available, such as CDK4/6, PI3K, mTOR, AKT (Dong et al., 2021) or PARP inhibitors, which allow for an individualized and targeted treatment (Nur Husna et al., 2018). Poly-ADP-ribose polymerase (PARP) inhibitors have emerged as an important new class of compounds for patients with MBC and an inherited BRCA1 or 2 mutation (Ditsch et al., 2024). In advanced and recurrent ovarian cancer with an HRD-profile including BRCA-mutation and non-BRCA-related situations, PARP inhibitors have contributed to an increase in time to progression and quality of life (Bruin et al., 2022) and, therefore, a change in the natural history of the disease.

In MBC, two PARP inhibitors, Olaparib and Talazoparib (Thill et al., 2023), are approved by the European Medicines Agency (EMA) and recommended by AGO (German Gynecological Oncology Group) together with Olaparib for high-risk early breast cancer (Morganti et al., 2023; Park-Simon et al., 2023). For the treatment of ovarian cancer, three PARP inhibitors, Olaparib, Rucaparib and Niraparib have been authorized for treatment in Europe (Bruin et al., 2022).

Patients' preferences for such modern oral anti-tumor therapies (Hester et al., 2024) result in prolonged therapy durations as well as an increase in personal empowerment and responsibility on behalf of the patient due to the reduction of medical consultations and the intake at home (Weingart et al., 2008). Altogether, this requires a change in patient care (Schlichtig et al., 2019).

Especially during the first three months of therapy, hematologic side effects, such as thrombocytopenia, leukopenia and anemia, occur frequently. Nausea, fatigue and diarrhea may also be common at the beginning (LaFargue et al., 2019). All side effects can be managed with treatment interruptions or dose modifications but require an experienced treatment team in terms of preventive and therapeutic measures, as well as comprehensive education and support of patients and their families (Riese et al., 2017). More individualized nursing care can provide relief and improve quality of life (QoL), as recently shown for breast cancer patients (Saltbæk et al., 2024).

Establishment of a nursing consultation session for patients with oral tumor therapy (OTT) in oncological practice requires partial delegation of medical activities to specially trained, non-physician staff. A nurse with additional training in oncology can form the point of intersection between treating physicians and patients with advanced cancer, providing assistance with self-management, empowerment, and eHealth-based documentation during long-time OTT. This concept has become highly appreciated by physicians, with the need of further promotion over the next few years (Kaiser et al., 2019). Close cooperation between medical staff and oncologists is an absolute prerequisite for such a consultation, especially in the outreach non-academic setting with its time and financial pressures as well as different resources and treatment realities compared to academic centers.

So far, standardized nursing consultation for patients treated with OTT is not part of clinical routine in Germany (Travi and Wuerstlein, 2021). Therefore, the CAMPA (Care improvement for advanced or metastatic breast and ovarian cancer patients treated with PARP-inhibitors) project was created.

In CAMPA, a nurse-led consultation session for patients under OTT was combined with use of the e-Health platform CANKADO for optimal therapy support and increase of adherence and QoL, as first demonstrated by PreCycle study (Harbeck et al., 2023), triggering patient-reported outcomes (PROs) and implementing direct interaction of patients and nurse.

2. Methods

2.1. Study design

CAMPA was a prospective, single-arm, longitudinal study to evaluate the effects of an additional nursing consultation for patients with gynecooncological and breast cancers treated with PARP-inhibitors as OTT. The study received a positive ethics vote from the Ethics Committee of the Medical department of LMU Munich in December 2021, starting with recruitment of patients in January 2022. It was a cooperation between LMU University Hospital in Munich and the oncology outreach center in Fürstenfeldbruck, Germany. All participants gave verbal and written informed consent. Follow-up visits were continued until February 2024, with the last patient completing one year under observation.

The trial was supported by patients' advocacy and interprofessional cooperation with KOK (Nursing in oncology of the German Cancer Society, DKG).

2.2. Participants

CAMPA included patients with advanced or metastatic breast or ovarian cancer treated at one of the two centers (LMU Munich or Fürstenfeldbruck) with in-label PARP inhibitors. In terms of management, patients' therapy adhered to all standards of care according to national and international guidelines in breast cancer (Thill et al., 2023; Ditsch et al., 2024; Gennari et al., 2021) and gynecological cancers (Colombo et al., 2023). Participants also gave consent to share anonymized data for educational purposes. After medical indication and discussion of further details about their new therapy by an oncologist, eligible patients were informed about the project by the nursing professional and were able to clear any questions before agreeing to participate.

2.3. Intervention

Patients were accompanied by additional specialized nursing care for one year. At baseline, medical history was taken and information about further appointments, drug interactions, and control of side effects provided. In subsequent visits, the nurse recorded adverse events (AEs), adherence, and quality of life (QoL) and gave suggestions for improvement of AE management in close cooperation with the oncologist (prescriptions, restaging). Information from baseline and follow-up visits once a month was documented in survey forms alongside self-reported satisfaction with care questionnaires at three predetermined points in time: At the beginning, after one month, during further course of treatment. Patients were also supported by eHealth: CANKADO platform allowed for documentation of QoL and daily tablet intake to increase adherence [PMID 37166817, 37201751].

Follow-up nursing consultations focused on: Drug intake, AE management, appointments, connecting to psychosocial support, preparing checklists for interaction, and discussion with the oncologist, handing out supporting tools such as medical plans, therapy calendars for drug intake and AEs, specific information material per substance, networks and apps (CANKADO). Before consulting the oncologist, another nursing task was to prepare blood values, cardiology and restaging documents or, if missing, acquire them. Counselling with patients and their family played an important role as well.

Ideally, through delegation of the above-mentioned tasks from the oncologist to the nurse, the aim was to reduce the time of the medical consultation with the oncologist, primarily consisting of initial indication, consenting, commenting on basic medical information regarding the planned OTT at first visit, alongside ongoing prescription of medication or supportive therapy in the further course after a brief handover by the nurse, providing preparatory work in person and by checklists.

This procedure was continued weekly in the first month in regular on-site visits, every 2 weeks during the second month and only once

every three or four weeks from month 3 onwards, depending on additional intravenous therapy, or, if desired, by telephone and mailing of laboratory results and prescriptions.

The nurse was in charge of coordination of this workflow and acted as the connecting link between the oncologist, further external medicals, patients, and their families.

2.4. Outcomes

The main objective was implementation and evaluation of a nursing consultation session for patients with gynecooncological and breast cancers receiving OTT with PARP inhibitors in an academic center and in non-academic outreach center as a pilot project as well as patients' satisfaction with this additional care. Therefore, adequate documentation of drug intake and health status on a regular basis for at least 18 days per month by at least 75% of participants within the first 6 months was set as primary endpoint to measure adherence. Patient reported information on consistent medication intake and its documentation were recorded using evaluation forms (reviewed by patient advocacy) developed for baseline and regular as well as irregular visits and later transferred pseudonymously to a study file. Any forgotten dosage or documentation was counted for each patient.

Overall satisfaction with care was recorded using self-generated questionnaires, reviewed by patient advocacy of the Ethics Committee of the Medical Faculty of LMU Munich. These surveys were carried out at three specific points in time: 1) before the nurse-led consultation, 2) after 1 month of therapy and 3) once during the course of therapy (month 4–6) or in case of an early drop-out, at the final consultation. A 6-point Likert Scale Chart with 6 levels of agreement/disagreement (0 = strongly disagree, 1 = disagree, 2 = rather not, 3 = rather agree, 4 = agree, 5 = strongly agree) was used to measure patients' self-assessed knowledge concerning medication in general, appointment scheduling, adverse events (AEs), management of AEs, emergency management as well as perception of the sufficiency of a doctor's consultation alone compared to an additional nursing consultation. At the final completion of the last questionnaire (evaluation form 3), overall satisfaction with care within CAMPA was tracked as well. In addition, a multiple-choice question asked for tools that helped patients the most: apps, psycho-oncological counselling, nutrition counselling, therapy calendars, physician's calls and calls by the nursing staff; multiple answers were allowed.

In three-month steps (month 1–3, 4–6, 7–9, 10–12) QoL was measured with EORTC QLQ-C30 (version 3.0) as a standardized questionnaire, with a specific focus on the sum of questions 29 and 30 (maximum 14 points) which was then converted into a percentage; perfect QoL was 100%.

Other secondary endpoints included dose interruptions, dose reductions, hospitalization, number of contacts, AEs and their severity using CTCAE (Common Terminology Criteria for Adverse Events) Grading (Freites-Martinez et al., 2021). They were tracked during the regular on-site visits (once a month) and evaluated, using three-month steps as well.

2.5. Statistical analysis

The ultimate sample size measured n = 50 patients with a drop-out rate of 50%. An intention-to-treat approach was applied for analysis of primary and secondary endpoints. The statistical software used was SPSS. Summary statistics for primary and secondary endpoints using three-month steps were calculated and testing for significant changes over time was applied with a significance level of 0.05 each.

For logistical reasons, the only exception with regard to time allocation were evaluation forms tracking satisfaction with care and the level of knowledge at three predetermined points: of particular importance was whether there was a change within the first month (evaluation form 1: start vs. evaluation form 2: after the first month). Apart from this, one single further follow-up was sufficient, especially as the variety in drop-out rate had to be taken into account.

A *t*-test for parametrically linked samples was utilized to analyze the number of contacts and the development over the course of treatment (month 1–3 vs. month 4–6 vs. month 7–9 vs. month 10–12) in order to test whether a reduction of contacts and thus support effort was significant ($p \leq 0.05$).

A Wilcoxon test for parametrically related samples was used for the distribution and comparison of the individual adverse events; a side effect was recorded as 'occurred' (=1) and counted for each patient if they had reported it at least once during the project, otherwise 'no occurrence' (=0) was counted; no multiple registrations per patient per side effect were possible. The aim was to rank the occurrence of side effects and to analyze if there was a significant difference between them.

For the development of quality of life (QoL), a *t*-test for paired samples was utilized and Spearman's rank correlation coefficient was used to test for direction and strength of the relationship between the occurrence and total number of side effects and change in QoL.

For analysis of the satisfaction with care evaluation forms, a paired sample sign test was applied. This was used to test whether patients considered a) the additional nursing consultation to be useful as a supplement to the doctor's consultation or b) not, with a significance level of 5% or lower. Patients were able to rate the corresponding statements on a 6-point Likert scale ranging from "0 = no agreement" to "5 = complete agreement" at three predetermined points in time – before therapy start, after one month and in the further course. Each patient's assessment and therefore rating of these two previous statements (doctor's consultation alone sufficient vs. additional nursing session necessary) over time (three several questionnaires) was compared with each other using a sign test for dependent, ordinal-scaled variables as well.

For a more precise measurement of care effort, the duration of doctor's and nursing consultations were tracked with these self-reported questionnaires and tested for a significant difference ($p \leq 0.05$) using a *t*-test for related samples.

95% Confidence Intervals for the following parameters were calculated using bootstrap method: mean age (years), time of hospitalization (days), duration of doctor's and nursing consultation (minutes), overall satisfaction with care (0–5 points), patients rating (0–5 points) on the need for the additional nursing care compared to physician's consultation alone (0–5 points).

3. Results

3.1. Participants and baseline characteristics

The patient population (n = 50) included 41 patients with ovarian cancer (OC) (82.0%), 4 with early breast cancer (EBC) (8.0%), one with metastatic breast cancer (MBC) (2.0%) and 4 with tubal cancer (8.0%). 21 patients with OC received a PARP inhibitor as first-line maintenance, 20 patients at a metastatic or recurrent stage. Fig. 1 shows the study enrolment and consort. The average age within the collective was 60.4 years [37; 86]. Baseline characteristics of participating patients are displayed in Table 1. With a total of 29 patients, the majority (58.0%) was treated with Olaparib, 18 with Niraparib (36.0%) and 3 with Rucaparib (6.0%). None received treatment with Talazoparib (0.0%). Out of 29 treated with Olaparib, 20 (40.0% of all patients) also received an infusion with Bevacizumab every 3 weeks, another 3 an additional therapy with Pembrolizumab, 2 with Letrozol and one bisphosphonate. The other 24 patients (48.0%) received a PARP-inhibitor as mono therapy. As far as relevant mutations are concerned, 18 patients (36.0%) were BRCA1/2 positive, 9 (18.0%) only HRD positive. In EBC and MBC all patients were BRCA positive.

Until the end of the project (02/24) n = 25 patients (50.0%) had completed one year of OTT with a PARP inhibitor and additional nursing consultation within CAMPA. A total of n = 25 (50.0%) dropped-out before completing one year, almost all because of progression and

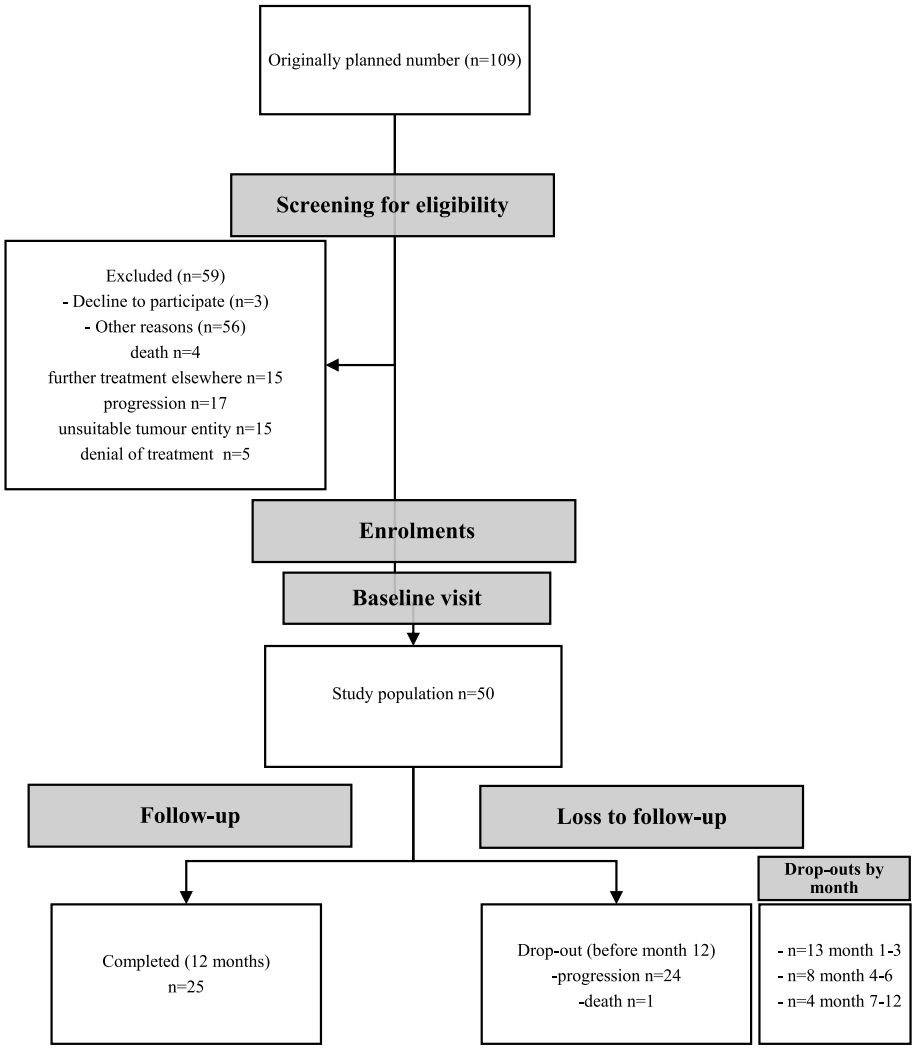

Fig. 1. Consort diagram CAMPA.

Table 1
Patient characteristics at baseline.

Characteristic	Patient population (n = 50)
Age (y)	60.4 [37; 86]
Tumor entity, n (%)	
ovarian cancer (first-line maintenance)	21 (42.0%)
ovarian cancer (metastatic & recurrent)	20 (40.0%)
breast (EBC)	4 (8.0%)
breast (MBC)	1 (2.0%)
tubal cancer	4 (8.0%)
PARP inhibitor, n (%)	
Olaparib	29 (58.0%)
Niraparib	18 (36.0%)
Rucaparib	3 (6.0%)
Talazoparib	0 (0.0%)
Tumor therapy, n (%)	
PARPi + Bevacizumab	20 (40.0%)
PARPi + Pembrolizumab	3 (6.0%)
PARPi + Letrozol	2 (4.0%)
PARPi + Bisphosphonate	1 (2.0%)
Mono therapy with PARPi	24 (48.0%)
Relevant mutations, n (%)	
gBRCA1/2+	18 (36.0%)
HRD+, gBRCA1/2-	9 (18.0%)
gBRCA1/2-, HRD-	23 (46.0%)

change in therapy (96.0%), one patient died (4.0%). Out of the 24 patients with progression, the majority was diagnosed with it at the beginning of OTT: 13 dropped out within the first three months of therapy (52.0%), another 8 between months 4 and 6 (32.0%), one in month 8 (4.0%) and 3 in month 9 (12.0%); no further drop-outs occurred past month 9. Mean duration within the project was 8.0 months (95% CI: 6.8–9.2).

3.2. Dose modification and side effects

A total of 20 dose reductions were seen in 18 out of 50 patients (36.0%). Two patients underwent two dose reductions, 16 patients only one. Additionally, 43 dose interruptions were performed on 26 patients (52.0%). In one case (2.0%), medication had to be interrupted four times, three patients (6.0%) had to pause three times, eight patients (16.0%) twice and 14 patients (28%0.0) once. No interruption was necessary for the remaining 24 (48.0%).

Anemia was the leading reason for interruption (25.6%), followed by Covid-19 (16.3%) and other infections (16.3%) especially including urinary tract infection (7.0%). Further interruption was due to surgery of any kind (9.3%), elevated liver enzymes (7.0%), nausea (4.7%) and other reasons such as fatigue and neutropenia (each 2.3%).

With over 90%, most AEs and therefore dose interruptions occurred within the first 3 months of OTT and stagnated after month 4.

In absolute terms, fatigue was the most common and persistent side effect, which was reported by 31 patients (62.0%) with a mean duration

of 6.4 months [3; 12], followed by nausea and vomiting, observed in 30 (60.0%) cases with a mean duration of 5.1 months [3; 12]. However, the overall occurrence of fatigue and nausea compared to other side effects was not significantly higher ($p > 0.05$), except for fatigue compared to diarrhea ($p = 0.026$) and nausea compared to taste disturbances ($p = 0.024$). Other typical AEs were diarrhea (reported by $n = 15$ patients), taste disturbances ($n = 13$), anemia ($n = 11$), polyneuropathy ($n = 11$) which had started during previous treatment with intravenous chemotherapy in all cases, pain ($n = 11$), dyspnea ($n = 9$), constipation ($n = 9$), dry skin and mucosa ($n = 7$), insomnia ($n = 7$), loss of appetite ($n = 7$), neutropenia ($n = 6$), urinary tract infection ($n = 5$), elevated liver enzymes ($n = 4$), rise in creatinine ($n = 4$) and tachycardia ($n = 1$). Table 2 shows the distribution of all side effect and their mean duration during the project. A side effect was recorded as 'occurred' (=1) and counted for a patient if they had reported it in at least one visit, otherwise 'no occurrence' (=0) was counted; multiple registrations per patient were not possible.

Overall, a significant ($p < 0.05$) reduction in quantity of AEs was recorded over time: In month 1–3, 98.0% of all patients suffered from side effects, 78.0% in month 4–6 (significant reduction, $p < 0.001$) and 60.0% in month 7–9 ($p = 0.009$). A correlation was found between the decreasing number of AEs and rising levels of quality of life: In months 7–9, increasing QoL and decreasing number of side effects even showed a strong and significant ($p = 0.003$) correlation (Spearman $|\rho| = 0.93$). After half a year of OTT, most severe side effects caused by PARP inhibitors had decreased to a minimum; the after-effects of previous chemotherapy treatments had started to disappear, which was observed for polyneuropathy after a carboplatin-based therapy, lasting approximately 8.5 months within CAMPA. Month 7–9 was also identified as a turning point in the development of care effort, as shown below.

3.3. Hospitalization

Another parameter considered was the number of hospitalizations within the collective: a total of 18 hospital admissions were documented for 15 of 50 patients (30.0%). Three patients were hospitalized twice. All admissions happened for surgical reasons: Abdominal surgery (33.3%) with four hernia operations and two stoma relocations, followed by 5 patients with eye surgery (27.8%) including four cataract and one ocular infarction surgery were the leading reasons for admission. Others (5.6% each) included surgery because of spine prolapse, breast cancer, tooth and jaw garnish, thyroid nodules, tracheostoma and DJ ureteral splint. Average hospitalization time was 13.7 days (95% CI: 6.0–16.2). Most hospitalizations were seen in patients with ovarian cancer, especially in case of post-surgical problems.

All patients with at least one hospitalization were part of the collective at university hospital. There were no hospital admissions among the patients treated at outreach center, among which the proportion of breast cancer patients (50.0%) was significantly higher ($p < 0.001$) than in the hospital collective (4.5%). This indicates a different initial situation regarding tumor entity and state of health of patients in the outreach center compared to the university hospital. Another indication for this is the mean duration within the project: among the outreach center collective, 83.3 % were in the project for 12 months, with only one outlier dropping out after 1 month because of progress. The mean duration was 10.2 months. However, due to the small number of only 6 patients at outreach center, no general statement can be made.

Table 2
Distribution and duration of side effects during CAMPA project.

Side effect	Number of patients (n = 50) with side effect	Duration of side effect (m), mean (SD)
Fatigue	31 (62.0%)	6.4 (3.9)
Nausea & vomiting	30 (60.0%)	5.1 (3.3)
Diarrhea	15 (30.0%)	4.0 (2.2)
Hospitalization	15 (30.0%)	0.5 (0.2)
Taste disturbances	13 (26.0%)	5.1 (2.8)
Anemia	11 (22.0%)	4.1 (1.5)
Polyneuropathy	11 (22.0%)	8.5 (4.0)
Dyspnea	9 (18.0%)	4.0 (2.1)
Constipation	9 (18.0%)	4.7 (2.2)
Dry skin & mucosa	7 (14.0%)	6.4 (3.2)
Insomnia	7 (14.0%)	4.3 (3.4)
Loss of appetite	7 (14.0%)	3.0 (0.0)
Neutropenia	6 (12.0%)	3.0 (0.0)
Urinary tract infection	5 (10.0%)	5.4 (2.5)
Elevated liver enzymes	4 (8.0%)	3.3 (2.1)
Rise in creatinine	4 (8.0%)	3.0 (0.0)
Tachycardia	1 (2.0%)	6.0 (0.0)

3.4. Care effort

Between the beginning (month 1–3) and further course of the project, a significant reduction in time resources was recorded ($p < 0.05$): Of the total number of $n = 1908$ contacts, 953 (49.9%) were counted within the first 3 months, including external appointments, blood tests, phone calls and regular as well as irregular visits.

In month 4–6, these contacts reduced significantly ($p < 0.001$) by almost half to 491 (25.7%) and another decrease to 331 (17.3%) in month 7–9 compared to month 4–6 ($p = 0.026$). The total number of contacts past month 9 was 133 (7.0%).

As previously noted, most progressions and drop-outs occurred before month 6 (84.0%). Nevertheless, only counting patients who had not yet been discharged at a certain point in time, using mean values of contacts per patient, they all differed significantly ($p < 0.05$). Testing even showed highly significant differences comparing month 1–3 and month 4–6, as well as the equivalent for month 7–9 and month 10–12 ($p < 0.001$). Fig. 2 shows the relative distribution of recorded contacts divided into regular visits, irregular visits, calls, blood tests – external and internal, at LMU university hospital – and external appointments such as cardiological ultrasound and restaging. It becomes clear how the ratios shifted over time: from contacts that required more time and care effort (regular and irregular visits, phone calls, external appointments) to contacts with lower face to face care requirements (blood tests), manageable by fax.

The average duration of doctor's consultation as reported by patients decreased significantly from 17.3 min (95% CI: 15.0–19.4) at the beginning (evaluation form 1) to 14.8 min (95% CI: 13.0–16.5) during more routinised visits ($p = 0.021$) as stated on the self-assessment questionnaires in the further course of the project (evaluation form 3). The duration of nursing consultation shortened as well: it reduced from initially 22.5 min (95% CI: 19.0–26.8) to 17.8 min (95% CI: 14.5–21.0), stated in evaluation form 3 ($p = 0.043$). Comparison between the duration of doctor's and nursing consultations showed a significant difference at the beginning (evaluation form 1) and the first month of OTT (evaluation form 2) ($p = 0.010$), with a certain late convergence (evaluation form 3) ($p = 0.339$). Fig. 3 displays the differences.

3.5. Quality of life and satisfaction with care

Before the first nursing consultation, patients rated their QoL with approximately 68.6% out of 100% at the beginning of OTT. Overall QoL increased to a maximum of 81.4% after month 9, however, the difference in QoL was not significant ($p > 0.05$).

With an average rating of 4.97 out of 5 points in the evaluation forms ($n = 37$), satisfaction with CAMPA care was very high (95% CI: 4.94–5.00). Regular phone calls after one week of therapy regarding tolerability and dosing (marked on 40.5% of all evaluation forms) alongside therapy calendars (29.7%) were considered the most helpful aids by patients and nurses. They were listed most frequently when asked for tools contributing most to their adherence and satisfaction with care, using multiple choice. Further answers reported were

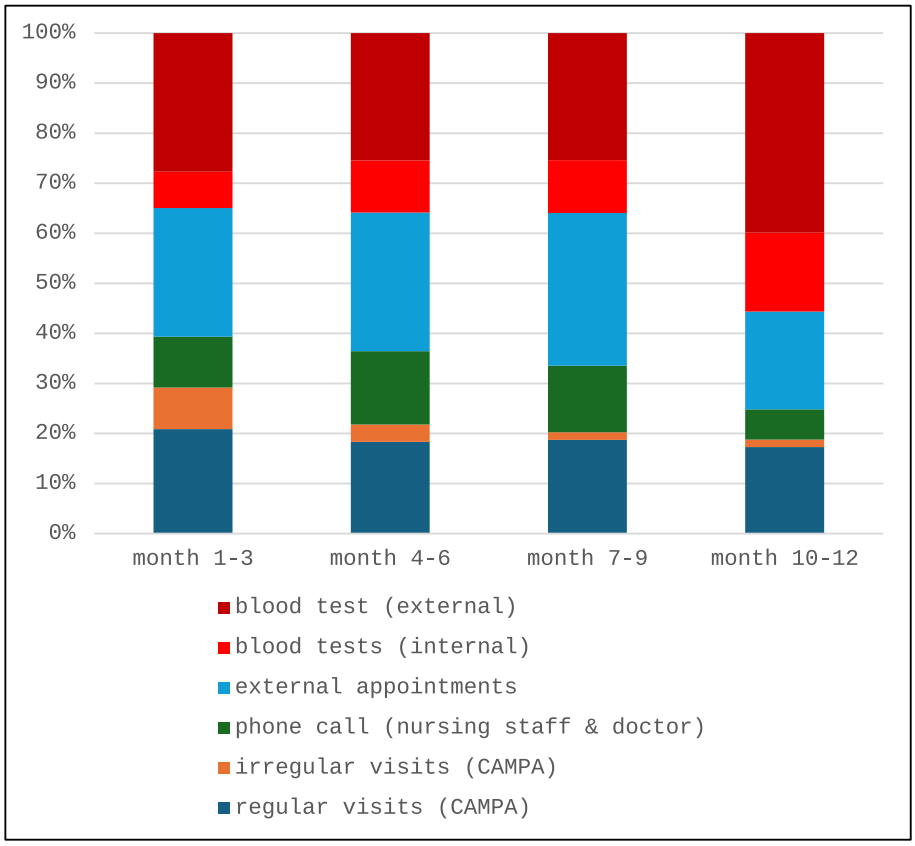

Fig. 2. Relative distribution of recorded contacts (n = 50) since 02/22.

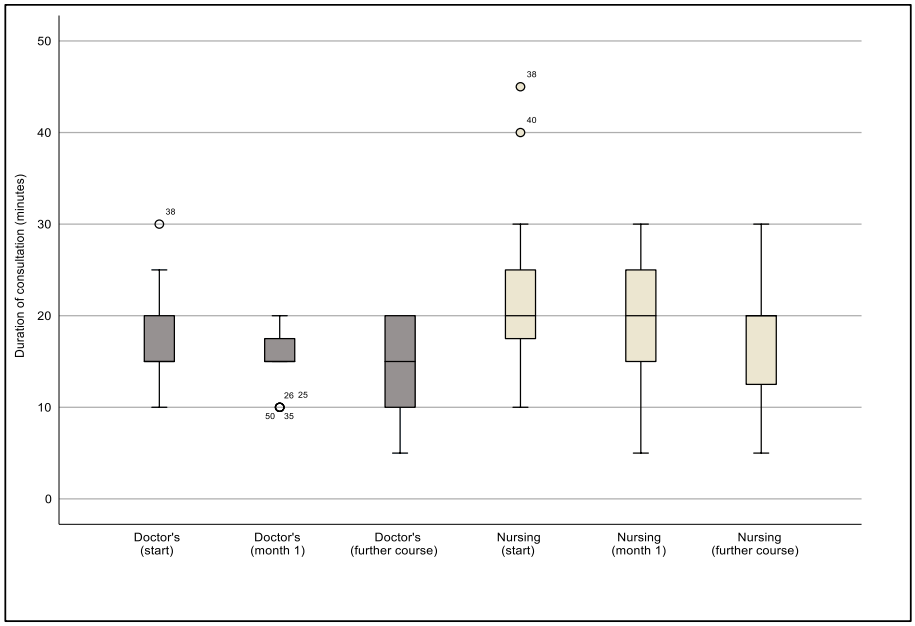

Fig. 3. Duration of doctor's and nursing consultation over the course of the project.

physician calls (29.7%), psycho-oncological support (13.5%) and nutritional counselling (2.7%).

Only 45.9 % fully agreed (5 out of 5 points) that the doctor's consultation alone was sufficient to provide adequate information. The answer was rated with an average of 4.35 points (95% CI: 4.16–4.54) compared to approximately 4.86 points (95% CI: 4.68–5.00) for the corresponding statement regarding the supplementary nursing consultation as an inevitable add-on. 94.6 % strongly agreed that the additional nursing consultation was needed to complete information. The difference between these two statements and their rating by patients was significant ($p = 0.021$) at the beginning (evaluation form 1), after one month of therapy (evaluation form 2) ($p = 0.002$) and even highly significant ($p < 0.001$) in the further course of the project (evaluation form 3). Fig. 4 shows the distribution of patients' answers on evaluation

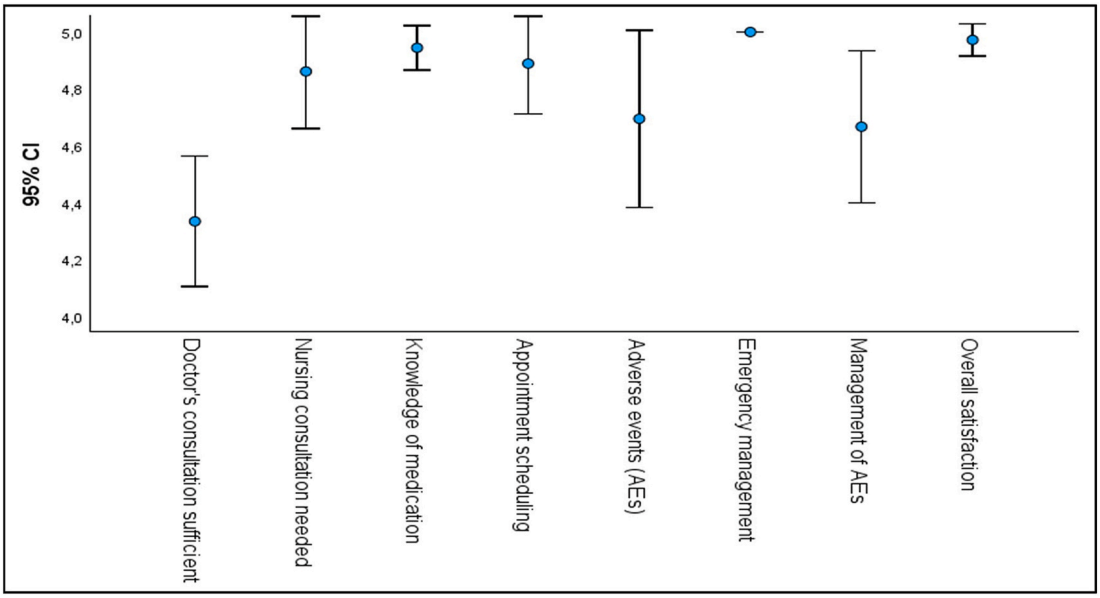

Fig. 4. Patients' self-assessed level of knowledge and satisfaction with care in the further course of the project (evaluation form 3) (n = 37), rated from 0 = strongly disagree to 5 = strongly agree.

form 3 (n = 37) with a self-assessment of knowledge concerning medication, appointments, side effects, AE management, behavior in case of emergency, as well as overall satisfaction with nursing care and individual need for the additional consultation session compared to a visit with the oncologist only.

3.6. Medication adherence and documentation of drug intake

Adequate documentation prior to drop-out or completion of six months of OTT was reached with a mean duration of non-documentation of 2.0 days [0; 7] per month. 10.0% of all patients stated they had forgotten to take their medication once during enrolment and therefore did not record drug intake on the corresponding day. Another 12.0% did not do any documentation. 78.0% reported to have taken medication and documented everything, even if they had a dose interruption, as we asked them to cross off those days in their therapy calendar.

4. Discussion

We used a one-phase observatory approach in a prospective single-arm study to evaluate the effects of an additional nursing consultation for patients with gynecooncological and breast cancers treated with PARP-inhibitors as oral tumor therapy (OTT) at an academic and non-academic outreach oncological center.

Overall, adherence measured by continuous documentation of medication intake as primary end point was high among patients (78.0%) and the criteria of adequate documentation for at least 18 days per month by at least 75% was met.

Patients' answers concerning their documentary at home was recorded during follow-up visits and forgotten medication intake and documentation were tracked. We cannot certainly know, whether regular recording and intake took place as patients stated or if they had forgotten more often. This was a balancing act between patients' autonomy and the exact collection of data, as we did not want to enforce participants to use an app or provide exact paper documentation at every visit.

Furthermore, another considerable restriction is the Hawthorne effect, stating that awareness of being under observation can change participants' behavior in favor of desired outcome (McCarney et al., 2007). It remains unclear whether adherence and documentation of drug intake would be the same in the context of a nurse-led consultation without participation in a study. Some sources even indicate over-adherence in such constellation (Komatsu et al., 2020).

The most patient-relevant endpoints included satisfaction with care, occurrence of adverse events (AEs) and improvement of quality of life (QoL); particularly relevant results for the treating team were the reduction in contacts and, consequently, minimization of time effort.

Close patient monitoring as well as optimized interprofessional management in OTT (Henze et al., 2023) appear as an important part of nursing care, which can help to improve QoL as suggested in literature comparing nurse-led interventions with non-nurse-led interventions for oncological patients (Cheng et al., 2018). As mentioned above, development of QoL and AEs showed a strong and significant ($p = 0.003$) inverse correlation (Spearman $|\rho| = 0.93$). Conversely, good side-effect management and therefore adequate patient care potentially have a positive effect on QoL. Even though we can only prove correlation not causality, the results concerning satisfaction with CAMPA care emphasize their individual benefits for patients as highly appreciated with an average rating of 4.97 out of 5 points on our self-generated questionnaires. The overall appreciation and recognized necessity of this additional consultation by the patients were significant at all times compared to a consultation only with the physician.

The issue of sufficient knowledge concerning side effects appears to be a highly sensitive matter for patients, as can be seen from the fact that self-assessed safety in dealing with AEs showed the widest spread within the collective (Fig. 4). Follow-up calls were supposed to offer the opportunity to ask questions about the management of side effects, preferably before or at the onset of their development to optimize the interception of their full manifestation.

In this context, the significant ($p < 0.05$) decrease in quantity of AEs over time with correlation to rising levels of QoL in CAMPA is essential for patient care. After half a year of OTT, most severe side effects had decreased to a minimum by adequate management and/or dose modification; most patients seemed to become accustomed to the less severe, but persistent AEs such as fatigue accepting them as part of everyday life. After-effects of prior chemotherapy such as polyneuropathy apparently started to disappear between month 7–9. These three months were also a turning point in the development of care effort with a highly significant reduction compared to month 4–6 ($p < 0.001$).

In CAMPA, anemia was the leading reason for interruption followed

by Covid-19 and other infections, elevated liver enzymes, nausea, fatigue, and neutropenia. Overall, the distribution of serious side effects found within CAMPA was consistent with the information provided by further studies with anemia being the most common severe AEs in patients with Olaparib (Colombo et al., 2021), followed by nausea and neutropenia. The percentage of patients with dose interruptions in CAMPA (52.0%) compared to previously mentioned studies for Olaparib (51.9%) and dose reduction (36.0%) in CAMPA compared to SOLO1 trial (28.5%) were very similar as well (Colombo et al., 2021).

Differences in percentage may be due to the range of PARP inhibitors used in the project, and their variation in the AE profile. Furthermore, Covid-19 has not been taken into account in previous studies yet (Colombo et al., 2021). In CAMPA, patients were instructed to pause medication until tested negative for Covid-19 and not showing symptoms anymore.

Another result open for discussion is the significant reduction of contacts ($p < 0.05$) and the question whether the additional consultation was the main reason for decreasing workload within the medical team. Particularly high care effort at the beginning (month 1–3) can be explained by more frequent regular visits, additional contacts in case of emergency – because of severe side effects and hospitalization – dose adjustment or questions concerning drug intake and AEs. A decrease in AEs generally seen in patients treated with Olaparib (Colombo et al., 2021) could possibly result by itself in a declining demand for further help. In CAMPA, introduction of standardized calls after one week of therapy and well-structured information material, such as therapy calendars made important contributions, as patients felt safer in their medication according to their responses, reducing the need for further irregular phone calls for reassurance of correct drug intake, behavior and intervals between blood tests. In the established follow-up calls, patients were asked to repeat the dosage and correct intake independently to check for any misunderstanding. This seemed to have helped to consolidate the right dosing regimen.

CAMPA as a pilot project has resulted in ongoing future tasks: For further establishment of an OncoCoach or contact person for patients under OTT, adequate standardized training as an oncology nurse or OncoCoach is essential with the potential of creating higher motivation among nurses to acquire additional qualifications at a time of labor shortage in the care sector (Welslau and Tesch, 2022). Of course, this represents an add-on workload for nursing staff. However, the opportunity to gain more personal responsibility as part of the delegation of medical tasks from the oncologist can increase their commitment. For this aim, it is important to improve interprofessional teamwork (Henze et al., 2023) and ensure good cooperation across all professions. This is particularly relevant for outreach practitioners and outreach centers. In fact, a shift of patients and of specialized oncological nurses from traditional hospitals towards outreach day-hospital centers, where work-life balance conditions are more attractive, has increased and is highly requested (Hermes-Moll and Heidt, 2019). While there is still considerable potential for expansion in Germany, the assumption of responsibility on the part of nursing care is already routine in Anglo-American countries (Douglas et al., 2018) and Sweden (Berglund et al., 2015) with a wide range of nurse-led services in oncology care including nurse-led clinics.

Therefore, clear rules for delegation are yet to be established within the healthcare system, as well as adequate salary for the additional services provided by nurses (Harbeck et al., 2022). There is high interest and demand, both on behalf of medical staff (Travi and Wuerstlein, 2021) as well as patients (Hester et al., 2024) with results from the IMPACT trial pointing out positive effects of supportive care programs for patients with breast cancer concerning therapy management and the consistency of medication intake and therefore adherence (Welslau et al., 2023).

From the co-operation with KOK (nursing in oncology), these results and experiences were passed on as an outreach initiative by the CAMPA investigators and will be published at a later time point.

4.1. Limitations

The originally planned time frame from September 2021–September 2023 was exceeded by 5 months due to a delayed ethics approval in 12/21. Recruitment of patients started immediately afterwards with the first patient starting on 12/01/22. Due to this initial delay, the intended target number of participants could not be achieved ($n = 50$ vs. $n = 109$).

Another barrier in clinical practice was the Covid-19 pandemic causing late visits and laboratory results due to covid infections.

The high drop-out rate of 50% primarily because of disease progressions and resulting therapy changes, and death (one patient) also required adjustment of the project. Our cohort mainly consisted of recurrent ovarian cancer patients treated at the university hospital with a progression-free survival of sometimes not more than 9 months (Katsuda et al., 2024), depending on the initial presentation. Therefore, the cohort required by the ethics proposal was probably not optimal to demonstrate long-term benefits of a nurse-led clinic and the results may have been clearer with recruitment of more breast cancer patients and treatment at the outreach center.

The originally planned comparison between hospital and oncology practice was not possible due to the small number of patients ($n = 6$) at the outreach cancer center Fürstenfeldbruck, partially caused by a contracting delay (first patient: 30/08/22), the Covid-19 pandemic and an overall smaller number of gynecological patients there, reflecting the real-world distributions of oncological patients in this treatment setting.

An interim discussion in September 2022 with all project participants refocused the project accordingly. Patient questionnaires were enriched, focusing on patients' satisfaction and improvement which in turn created the need for additional amendments and ethic votes.

Last but not least, there was no control group to find out whether the significant results regarding improved QoL were actually due to the nursing consultation itself.

5. Conclusions

CAMPA showed that standardized nursing consultation for patients treated with OTT is a highly appreciated effort in academic and non-academic institutions with positive response. This contributes to OTT adherence, as measured by adequate documentation of drug intake on a regular basis, and to improvement of QoL. Furthermore, it provides an excellent addition to the doctor's consultation as stated by patients. In particular, nursing calls after one week to ensure right dosing and ask for problems concerning AEs and their management alongside therapy calendars are considered two of the most helpful tools according to patients' response.

In particular during the first three months, this additional approach helped to significantly reduce time and care efforts for physicians and resulted in a more competent and self-confident nurse-driven consultation. The effect of this delegation not only improves the quality of interprofessional care, but also augments motivation and responsibility of oncological nurses who play a key role in cancer care in academic and non-academic institutions.

Digitalization in health care is necessary and will become mandatory in the future, with evidence-based applications such as CANKADO simplifying preparation for follow-up consultations as well as documentation of AEs and QoL. The addition of onco-coaching optimizes processes and resources in the face of increasing numbers of OTT patients and individualization of patient care.

In conclusion, we intend to disseminate these experiences within the medical community and propose such a model for nurse-led consultations as a part of future routine care in academic and non-academic institutions for the German and other health systems where this interdisciplinary care is still lacking.

CRediT authorship contribution statement

Lisa Hirschberg: Writing – review & editing, Writing – original draft, Visualization, Resources, Investigation, Formal analysis. **Franziska Henze:** Writing – review & editing, Validation, Resources, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Kerstin Paradies:** Writing – review & editing, Conceptualization. **Sophie Winkler:** Writing – review & editing, Resources, Investigation. **Timo Schinköthe:** Writing – review & editing, Conceptualization. **Renate Haidinger:** Writing – review & editing, Conceptualization. **Ronald Kates:** Software, Data curation, Conceptualization. **Dirk Hempel:** Writing – review & editing, Conceptualization. **Sven Mahner:** Writing – review & editing, Conceptualization. **Bernd Kost:** Writing – review & editing, Conceptualization. **Alexander Koenig:** Writing – review & editing, Conceptualization. **Kristina Lippach:** Writing – review & editing, Conceptualization. **Fabian Trillsch:** Writing – review & editing, Conceptualization. **Sebastian Theurich:** Writing – review & editing, Conceptualization. **Nadia Harbeck:** Writing – review & editing, Conceptualization. **Valeria Milani:** Writing – review & editing, Conceptualization. **Rachel Wuerstlein:** Writing – review & editing, Visualization, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

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