



Sharing Progress
in Cancer Care

QUALITY OF CARE IMPROVEMENT IN MBC PATIENTS INVESTIGATORS MEETING

Lisbon - 8 November 2023

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CAMPA

Care improvement for metastatic breast and ovarian cancer patients treated with PARP-inhibitors

Results at SPCC Quality of Care Improvement in MBC Patients Investigators Meeting

Breast Center, Dept of Gynecology and Obstetrics and CCC Munich, LMU University Hospital,
LMU Munich, Germany

11/23

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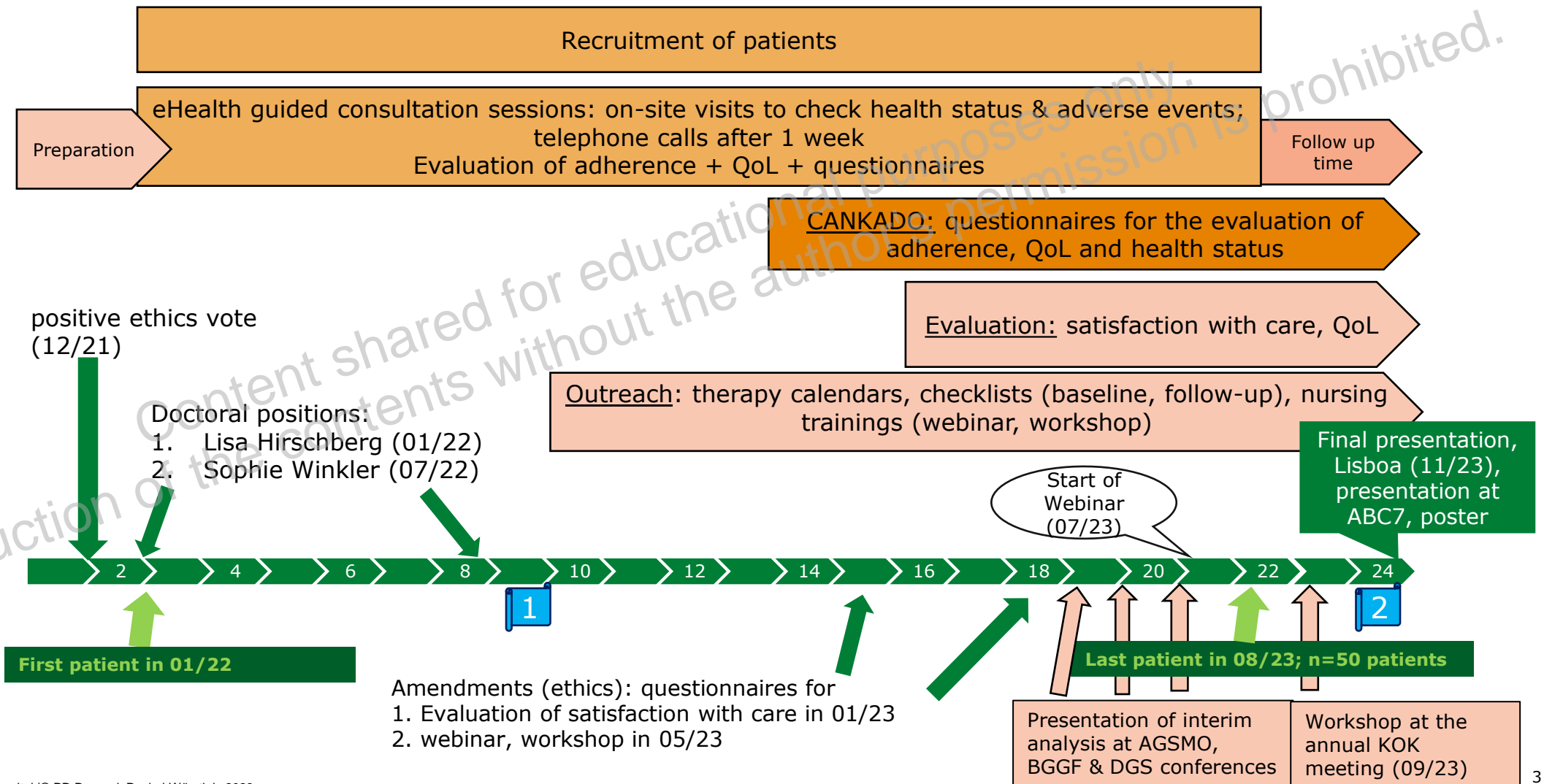


Pflegekompetenz in der Onkologie

1. Timeline and amendments

- 2 publications:**
- 1 Pflegeexpertinnen begleiten orale Tumorthherapie. *Die Schwester Der Pfleger* (08/2022) [1]
 - 2 Interprofessionelles Management der oralen Tumorthherapie. *Im Fokus Onkologie* (2023) [3]

- Team meetings (n=11):**
- 29/11/21 Initiation with all involved parties
 - 06/12/21 Presentation in the regular Monday training at LMU university hospital
 - 02/03/22 Information for day clinic at LMU university hospital
 - 27/07/22 training Dr. Milani (oncology practice in Fürstenfeldbruck) with RW
 - 21/09/22 - Interim evaluation with all involved parties; further procedure (RW, FH, LH, SW):
 - 22/11/22
 - 21/12/22
 - 08/02/23
 - 20/04/23
 - 15/06/23
 - 14/08/23
 - 04/10/23
 - 30/10/23 meeting with the oncology practice in FFB
 - 03/11/23 Webex meeting with all involved parties



2. Project

Project description

CAMPA - Care improvement for metastatic breast and ovarian cancer patients treated with PARP-inhibitors

- Evaluation and Outreach of consultation session for patients receiving oral therapy with PARP-inhibitors
- Initiation: 29/11/21; positive ethics vote: 12/21
- **Part 1: Patient project (pilot)**
 - **Total patient population: n=50** patients treated with PARP-inhibitors; originally planned number: n=109 (not reached due to Covid-19, time, additional amendments, development of new questionnaires)
 - **Duration: 1 year of observance**; ongoing onsite visits every month
 - **Inclusion criteria / Exclusion criteria**
 - A) Patients under OTT with a PARP inhibitor / other than PARP inhibitors due to advanced or metastatic breast cancer or advanced ovarian cancer
 - B) Willingness to share anonymized data retrieval during OTT visits / no consent to participate

→ Pilot project with 2 participating centers → experiences → outreach

Patient project (LMU, FFB)		
First visit	Between on-site visits	Subsequent visits
<ul style="list-style-type: none"> • Patient coaching in therapy management • First documentation of QoL • Carrying out blood tests and apparatus studies (e.g. ECG) • Introduction to CANKADO 	<ul style="list-style-type: none"> • Daily documentation of drug intake • Daily documentation of QoL • Documentation of side effects • Physician's consultation in case of adverse events • Individual care consultations if needed 	<ul style="list-style-type: none"> • Documentation and evaluation of side effects • Recording of patient's adherence • documentation of QoL before next visit takes place • Carrying out blood tests and apparatus studies (e.g. ECG)



Primary Endpoint	
adequate documentation of drug intake and health status on a regular basis over a 6-month period	
Secondary Endpoint	
Global health status (EQ-VAS) distribution	
Adherence regarding drug intake	
Dose interruptions	
Dose reductions	
Results of additional questionnaires regarding QoL, which are automatically opened by "triggering events", i.e., significant changes in health status according to EQ-VAS	EORTC QLQ-C30 (version 3.0) FACT B EQ-5D-5L

Fig. 1+2: Endpoints & project parts

2. Project

Project description

CAMPA - Care improvement for metastatic breast and ovarian cancer patients treated with PARP-inhibitors

- **Part 2: Outreach + Evaluation:** Transfer pilot → universal management
 - Evaluation of **CANKADO documentation, questionnaires, satisfaction with care**
 - Optimization of resources within the oncological team
 - development of **information material & standardized nursing training** and consultation; comparison: clinic / practice
 - Implementation of a **webinar and a workshop** for nurses → **Evaluation** of knowledge before/after → Comparison webinar / workshop
 - Publications

Evaluation (LMU, KOK)

Comparing the procedure and highlighting the differences in both day care clinics

Evaluated parameters

- QoL questionnaires
- adherence
- Side effects
- Therapy management
- Dose interruptions and dose reductions
- Questionnaires concerning satisfaction with care

Outreach (LMU, KOK)

Share results with medical community

- Publications for oncologists and nurses
- Experience of oncological nurse
- Educationals and interactive discussions for nursing professionals
- Implementation of a webinar & workshop for nurses → Evaluation of knowledge before/after → Comparison webinar / workshop

3. Results

Nursing consultation under OTT (PARP)

- Since **01/2022**: Implementation of a complementary nursing consultation at LMU university hospital (first patient: 11/1/22) (n=44) & oncology practice in FFB (n=6)
- Total patient population: n=50; age: 61.7 years [37; 86]
- 1 year completed: 13 patients
- Ongoing: 15 patients (status: **10/2023**)
- Drop-outs: 22 patients
 - 21 progression
 - 1 death
- Inpatient admissions: 15 hospital admissions (12 of 50 patients)
- Total number of dose reductions: 18
- Number of patients with dose reduction: 17
 - 1 patient with 2 dose reductions
 - 16 patients with 1 reduction
- Total number of interruptions: 38
- Number of patients with dose interruption: 24
 - 1 patient with 4 interruptions
 - 3 patients with 3 interruption
 - 5 patients with 2 interruptions
 - 15 patients with 1 interruption
- **Anemia as leading reason for interruption(27%),** followed by Covid 19 (24%) and fatigue (16%)

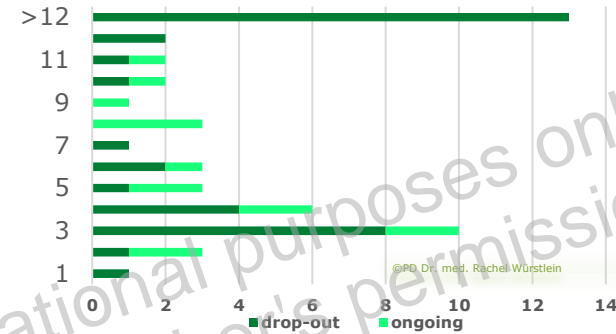


Fig. 3: Duration of PARP inhibitor therapy (in months)

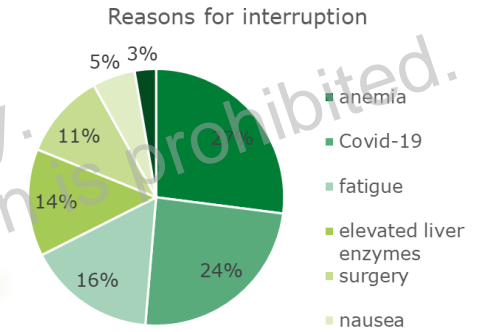


Fig. 4: Reasons for dose interruption (n=50)

Tumor entity	n=50 patients	Distribution
Ovarian cancer	41	82%
Tubal cancer	4	8%
Breast cancer	5	10%
PARP inhibitor		
Olaparib	29	58%
Niraparib	18	36%
Rucaparib	3	6%
Talazoparib	0	0%
Tumor therapy		
PARPi + Bevacizumab	20	40%
PARPi + Pembrolizumab	3	6%
PARPi + Letrozol	2	4%
PARPi + Bondronat	1	2%
Mono therapy with PARPi	24	48%
Relevant mutations		
gBRCA1/2+	18	36%
HRD+	9	18%
gBRCA1/2-, HRD-	23	46%

Fig. 5: Distribution of tumor entity, therapy and relevant mutations (n=50)

3. Results

Nursing consultation under OTT (PARP)

Result 1: Time resources (n=50):

- **Month 1-3:** higher care effort (more frequent visits, additional contacts, laboratory value checks)
- **Month 4:** decrease (very individual)
- From month 5 on: routine in procedure, fixed dose, fewer queries/calls

→ The more successful the initial consultation, the less follow-up work is required

→ Goal: optimal coordination, information, support

→ workload of the entire team (medical + nursing) is thereby clearly structured, reduced & channeled

Result 2:

- Especially in the first months of therapy, close patient monitoring is important for the improvement of quality of life + adherence (and thus: therapy effect)
- increase in adherence and quality of life through nursing consultations

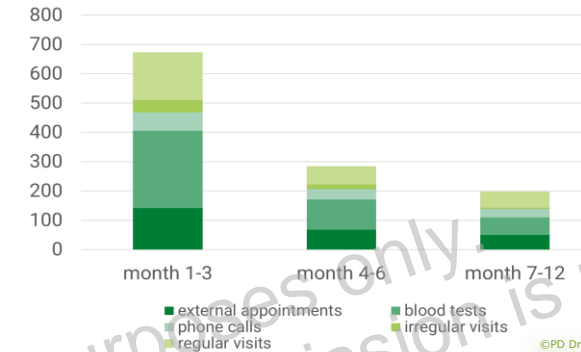


Fig. 6: Distribution of the total number of recorded contacts (n=50) since 02/22

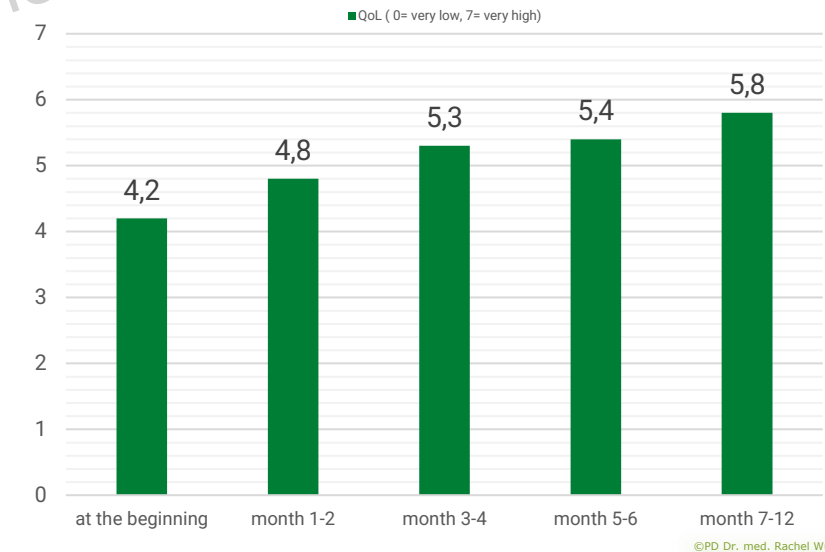


Fig. 7: : Development of quality of life under therapy support by a nurse-assisted consultation

3. Results

Nursing consultation under OTT (PARP)

Benefits of optimal nursing consultation for OTT

- 1. **Practical experience:** particularly helpful tools
 - Phone calls after 1 week (regarding tolerability & dosing)
 - Therapy calendar (product specific; paper or app)
 - checklists
- 2. **CANKADO PRO-React Onco**
 - Digital therapy calendar
 - Symptom specific behavior
 - Connection with medical consultants
 - direct intervention available
 - More individual care, simple and on time ways of communication

Kontrollbogen – Baseline Visite		[] Verhalten bei Überdosierung/Vergessener Dosis	
für Herr/Frau _____, geb. _____; Arzt/Ärztin: _____		Einnahme der nächsten Dosis zum regulären Zeitpunkt (NICHT doppelte Dosis)	
Medikament: (Basierung unterstreichen) <input type="checkbox"/> Olaparib (150/100 mg) <input type="checkbox"/> Niraparib (100 mg) <input type="checkbox"/> Talazoparib (0,25mg / 1 mg) <input type="checkbox"/> Rucaparib (300/250/200 mg)	Schema: x täglich: _____ mg (empfohlene Startdosis: - Olaparib – 2x tgl.: 2x 150 mg = 600 mg / Tag - Niraparib – 1xtgl.: 2x100mg = 200 mg/Tag - Talazoparib: 1xtgl.: 1x1 mg = 1 mg/Tag - Rucaparib: 2x tgl.: 2x300mg = 1.200mg/Tag)	Spezifische NW Gastrointestinal (Übelkeit/Erbrechen, Durchfall/Obstipation), Müdigkeit, Blutbildveränderungen (Anämie, Thrombozytopenie, Granulozytopenie), Nierenwertveränderungen, Leberwerterhöhungen, Geschmacksveränderungen, PNP, Muskelkrämpfe, Appetitverlust, Hautveränderungen, Hypertonie, HWI, Kurzatmigkeit, Schlafstörung	
Weitere Medikation: <input type="checkbox"/> Bevacizumab (i.v.) <input type="checkbox"/> Drononrat <input type="checkbox"/> sonstige		[] NW-Management Konservative Maßnahmen / Medikation (notfallmäßig: z.B. MCP, Loperamid zu Hause bereit haben)	
Datum der Dokumentation: Beginn der Einnahme:		[] Wechselwirkungen Medikamente (Antibiotika), Nahrungsergänzungsmittel, Nahrungsmittel (CAVE Grapefruit, Johanniskraut) -> zuvor Abklärung	
Vitalzeichen (Gewicht, Größe, Blutdruck, Puls)		[] Termine/Untersuchungen Regelmäßige Herzultraschall, Zahnarzt, Blutbild, Gynäkologie Kontrollen; Bildgebung	
Tumorentität:	<input type="checkbox"/> metastasiertes/fortgeschrittenes Mamma-CA <input type="checkbox"/> metastasiertes/fortgeschrittenes Ovarial-CA <input type="checkbox"/> Ovarial-CA (Rezidiv)	[] Reisen/Reha Reizeptaustellung [] OPs/medizin. Eingriffe Rücksprache (ggf. Pausierung)	
Menopausenstatus	<input type="checkbox"/> prämenopausal <input type="checkbox"/> postmenopausal <input type="checkbox"/> perimenopausal <input type="checkbox"/> unklar (Datum der letzten Untersuchung)	[] Unterstützende Angebote <ul style="list-style-type: none"> - Psychoonkologie - Ernährung - Komplementärmedizin - Bewegungstherapie/ Sportangebote - Sozialdienst 	
Relevante Untersuchungen vor Start:	Diagnose, Therapie:	[] Notfälle Ansprechpartner, Verhalten im Notfall (sofortiges Absetzen bei Fieber/AZ-Verschlechterung), Infomaterial aushändigen	
<input type="checkbox"/> Laborwertkontrolle <input type="checkbox"/> Herzultraschall <input type="checkbox"/> Gynäkologische Nachsorge <input type="checkbox"/> Zahnarzt <input type="checkbox"/> Bildgebung		[] Laborwertkontrollen Olaparib: 1x/Woche (1. Monat) -> alle 2 Wochen -> alle 4 Wochen Niraparib: 1x/Woche (1. Monat), dann alle 4 Wochen + RR-Kontrolle wöchentlich in den ersten 2 Monaten, dann 1x/Monat Rucaparib, Talazoparib: 1x/Woche (1. Monat), dann 1x/Monat	
Relevante Vorerkrankungen		Fragen/Anmerkungen	
<input type="checkbox"/> Magen-/Darmkrankung <input type="checkbox"/> Nierenerkrankung <input type="checkbox"/> Lebererkrankung <input type="checkbox"/> Lungenerkrankung <input type="checkbox"/> Herz/Kreislaufkrankung <input type="checkbox"/> Neurologische Erkrankung <input type="checkbox"/> Endokrine Erkrankungen (Bsp: Schilddrüse/Diabetes mellitus) <input type="checkbox"/> Hauterkrankung <input type="checkbox"/> Gerinnungsstörung <input type="checkbox"/> Allergien/intoleranzen		Kontaktdaten (+ ggf. Angehörige)	
Aufklärung		Datum & Unterschrift Mitarbeiter/In der Therapie: Datum & Unterschrift Arzt/Ärztin:	
<input type="checkbox"/> Wirkweise PARPI <input type="checkbox"/> Korrekte Einnahme <input type="checkbox"/> Aufbewahrung <input type="checkbox"/> Verweis auf Einnahmehilfen	Wirkung auf die DNA Unzerdrückt, unzerkaut, im Ganzen, am besten mit viel Flüssigkeit; regelmäßig (gleiche Zeit, falls 2x tgl.: ca. 12 h Abstand) Schutz vor Hitze, Sonne, Feuchtigkeit Patienten/-innen Tagebuch, Kalender, Handywecker/-app	©PD Dr. med. Rachel Würstlein	

Patienteninformation - Talazoparib																																																																																																																																																																																																																																													
Sehr geehrte(r) Patient/in Sie erhalten aktuell eine Erhaltungstherapie mit dem PARP-Inhibitor Talazoparib und müssen dafür in regelmäßigen Abständen Ihre Blutwerte kontrollieren lassen. Diese Information soll Ihnen eine Übersicht geben, um Sie mit Ihrer Therapie zu unterstützen. Einnahme Talazoparib: Tag 1 bis Tag 28 (durchgehend) 1x täglich _____ mg (Gesamtdosis: _____ mg / Tag) Im ersten Zyklus unter Talazoparib erfolgen die Blutabnahmen wöchentlich , dazu einmal im Monat zum anschließenden Kontrollbesuch.	Was Sie sonst noch wissen sollten Während der Einnahme von Talazoparib kann es zu Blutbildveränderungen kommen. Dies kann Symptome von Müdigkeit oder Kurzatmigkeit auslösen. Sollten Sie Fieber oder andere auffällige Symptome bemerken, melden Sie sich bitte umgehend in der Städt.Praxis oder über die Notfall-Telefonnummer bei unserem Dienstarzt. Bitte besprechen Sie die Einnahme neuer Medikamente – egal ob verschreibungspflichtig oder frei verkäuflich – zuerst mit Ihrem Behandlungsteam bei uns. Vermeiden Sie während der gesamten Einnahme von Talazoparib auf Grapefruitprodukte und Johanniskraut. Bitte führen Sie immer Ihr Tumorkonferenzprotokoll und aktuellen Medikationsplan (Apothek) mit sich.																																																																																																																																																																																																																																												
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Fig. 8 + 9 : Checklist baseline visit & therapy calendar (example: Talazoparib [4])

3. Results

Nursing consultation under OTT (PARP)

1. **Overview of the numbers of OTT** in the individual department
2. **Team decisions** with the practice / department management and colleagues
3. **Education:** Detailed knowledge of disease, therapy and support
4. **Redistribution** of time & processes within the team (change management)
5. **Space** (consulting room)
6. **Information for patients and family**
7. **Organization of delegation and communication** between physician, nursing and other staff (**checklists**)
8. **Appointment calendars** for planned visits
9. **Network for support offers** (local/regional)

10. Network for OTT (KOK)

11. Confidence in nurses' ideas

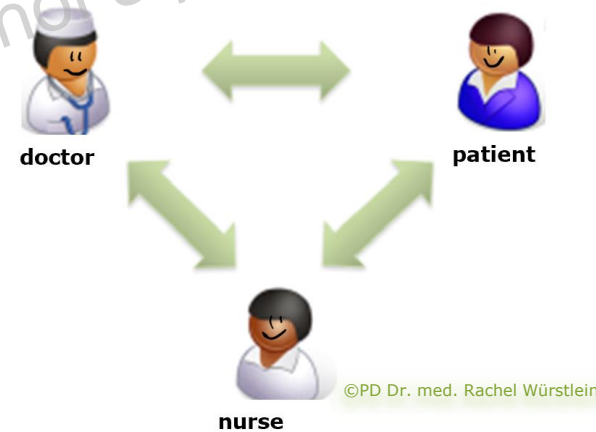


Fig. 10: Successful implementation of nursing consultation in OTT

4. Outreach

Workshop at the annual KOK meeting 09/2023)

Location: annual KOK meeting in Berlin (08-09/09/23)

Content: Interactive workshop on the implementation of nurse-led consultations in OTT

Participants: (n=22), attends: 250

- A total of 22 participants, 20 of whom were nurses and 2 of whom were medical assistants
- Median Age: 39.8 years [28;61]
- Median 7.4 years of experience with OTT [0;27]
- Majority of participants had advanced training in oncology (95%)



Fig. 11: Workshop for nursing staff at the annual KOK meeting in Berlin (08-09/09/23)



Fig. 12: CAMPA team (from right to left): PD Dr. Rachel Würstlein, Kerstin Paradies (KOK), Sophie Winkler, Franziska Henze, Lisa Hirschberg

4. Outreach

On demand Webinar

Content: Webinar on the implementation of nurse-led consultations in OTT

Availability: Accessible online on demand since 01.07.2023

Promotion: Distribution numbers of the KOK (n=1299), the WSG (n=1330), the LMU clinic (n=50), the project group Mamma (n=157), the Newsletter BC (n =1500) the network studies LMU (n=50) and a KOK training at Munich (n=50)

Participants (first 52 of the pre webinar survey)

- 67% nurses and 17% medical assistants
- Median age: 46 years [21;64]
- Average 6.83 years of experience with OTT [0;25]
- Most participants had advanced training in oncology (75%)
- Evaluation: ongoing



Fig. 13: QR Code webinar login

LMU KLINIKUM
Klinik und Poliklinik für
Frauenheilkunde und Geburtshilfe

EINLADUNG ZUM WEBINAR
für Pflegekräfte und MFAs in der Onkologie

**Pflegesprechstunde für Patienten/-Innen unter oraler Tumorthherapie (OTT),
Schwerpunkt in der Gynäkoonkologie (Mammakarzinom, Ovarialkarzinom)**

Ein Angebot der Konferenz onkologischer Kranken- und Kinderkrankenpflege (KOK)
in Kooperation mit dem Team Brustzentrum am LMU Klinikum, München

**Implementierung einer pflegebegleiteten
Sprechstunde für Patienten/-innen unter OTT**

■ **Warum brauchen wir eine zusätzliche
Pflegesprechstunde?**

■ **Was brauche ich für die Implementierung?**

■ **Was ändert sich in der Betreuung?**

→ **Praxistipps**

Wann & Wo?

- ab 01.07.23 online verfügbar (Dauer: 45 Minuten)

Warum profitiere ich von der Teilnahme?

- Informationen, Material und Tipps für die Durchführung einer Pflegesprechstunde

Warum profitieren unsere Patienten/-innen?

- Ziel: Optimaler Outcome für Patient/-in in Hinblick auf Adhärenz, Nebenwirkungsmanagement, Lebensqualität
- Therapieerfolg

Erfahrungen aus dem Projekt:

- CAMPA (Care improvement for metastatic breast and ovarian cancer patients treated with PARP-inhibitors)

Anmeldung für das Webinar:

- E-Mail: studienzentrale-brustzentrum-gh@med.uni-muenchen.de
- oder QR-Code 1
- Alle weiteren Informationen senden wir Ihnen im Anschluss per E-Mail zu.

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⁵CAMKADO Online-Ökosystem, Forschungszentrum Smart Digital Health, Universität der Bundeswehr München

Cooperation partners: Breast Center, Gynecological Cancer Center, KOK, DTK, etc.

Fig. 14: Webinar - information

4. Outreach

Workshop & Webinar

Comparison Workshop and Webinar

- What form of training do nurses prefer?
 - Workshop participants: 48% Webinar, 52% on site
 - Webinar participants: 71% Webinar, 29 % on site
- Self-assessment PARP inhibitors (0-100%):
 - gain of knowledge by >40 % workshop participants, >30% webinar participants
- Already an additional nursing consultation at the place of work
 - Webinar participants: 27% Yes, 72% No
 - Workshop participants: 32% Yes, 68% No
- What do nurses need to implement a nursing consultation for OTT?
(Results of an open question with 15 webinar participants and 7 workshop participants)
 - Checklists / guidelines (n=10 webinar) (n= 3 workshop)
 - Better facilities (n=3 webinar) (n=2 workshop)
 - More time (n=4 webinar) (n=2 workshop)
 - Studies as a basis for billability (n=2 webinar) (n=1 workshop)
 - Better communication (n=2 webinar)
 - Apps (n=1 workshop)

- Discrepancy between what nurses actually use and what they think is useful
→ Digital health applications and checklists in particular are highly appreciated by nursing staff in both the webinar and the workshop, but rarely used in practice.

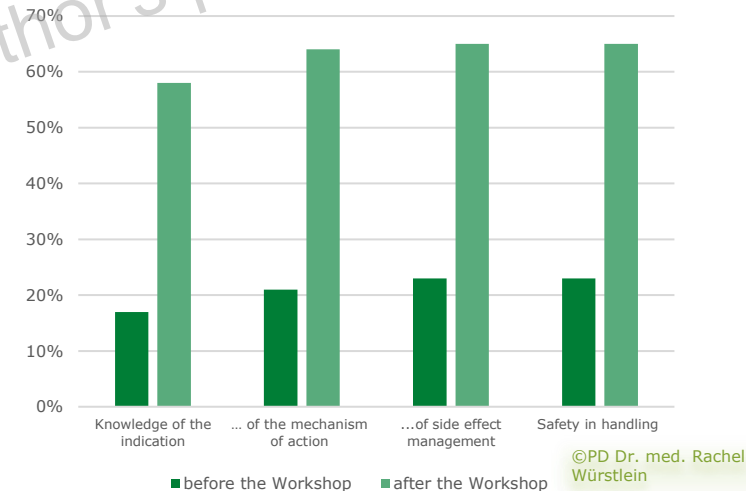


Fig. 15: Self assessment PARP inhibitors before and after the workshop (n=22) (unpublished data)

4. Outreach

Publications

Already published:

1) Topic: Oral tumor therapy in breast carcinoma

- Travi C., Würstlein R. **Orale Tumorthherapie beim Mammakarzinom.** *Pflegezeitschrift*, 2021; 74: 50-53.[1]

2) Topic: Nursing experts accompany patients' oral tumor therapy

- Harbeck N., Haupt J., Henze F., König A., Lippach K., Würstlein R. **Pflegeexpertinnen begleiten orale Tumorthherapie.** *Die Schwester Der Pfleger*, 2022; 60 (9): 42-47. [2]

3) Topic: Interprofessional management for patients with oral tumor therapy

- Henze F., Bornemann K., Haupt J., König A., Ortner P., Harbeck N., Würstlein R. **Interprofessionelles Management der oralen Tumorthherapie.** *Im Fokus Onkologie*, 2023; 26 (5): 18-23. [3]

Poster (4 published):

- AGSMO (online) – 13/05/23 – 'Therapiebegleitung durch eine standardisierte Pflegesprechstunde für Patient/-innen unter Oraler Tumorthherapie in der gynäkologischen Onkologie'
- BGGF Würzburg - 14-15/06/23 – 'Interimsanalyse einer ergänzenden Pflegesprechstunde für Patienten/-innen unter oraler Tumorthherapie in der gynäkologischen Onkologie'
- DGS Munich – 06-08/07/23 – 'Therapiebegleitung durch eine standardisierte, pflegerisch geleitete Sprechstunde für Patient/-innen, die eine orale Tumorthherapie mit einem PARP-Inhibitor erhalten'
- ABC7 – 09-11/11/23 - 'Therapy support with a standardized nursing consultation for patients under oral tumor therapy in the gynecological oncology (breast cancer and ovarian cancer)'

Two full publications (work in progress)

- a) **Evaluation of therapy support through a standardized nursing consultation for patients undergoing oral tumor therapy in gynecological oncology within the prospective CAMPA initiative** (when all patients have completed one year)
- b) **Outreach and evaluation of an interprofessional webinar and workshop within the prospective CAMPA initiative** (when the evaluation of the webinar and the comparison between webinar & workshop are completed)



Fig. 16: Publication "Pflegeexpertinnen begleiten orale Tumorthherapie" in "Die Schwester Der Pfleger" [2]

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Fig. 17: Publication "Interprofessionelles Management der oralen Tumorthherapie" in "Im Fokus Onkologie" [3]

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5. Summary

Conclusions, impact on the healthcare community

CAMPA - Care improvement for metastatic breast and ovarian cancer patients treated with PARP-inhibitors

1. Patients: Pilot for 50 patients with OTT PARP inhibitors & nursing consultations

- **positive response** (With an average of 4.95 out of 5 points, satisfaction with CAMPA care is very high)
- Especially in the first months of OTT, intensified care is essential for **QoL, adherence and management of AEs** (reduction of additional contacts → workload of the entire team is thereby clearly structured, reduced & channeled)
- Nursing consultation from 1st visit on as an important contribution to the increasing number of patients under OTT

2. Tools: Calls, Therapy calendar as the 2 most helpful tools (according to patients' response)

- **Phone calls after 1 week** (regarding tolerability & dosing)
- **Therapy calendar** (product specific; paper or app)

3. Nursing staff requires: Standardized nursing training

- Basic information (drug efficacy, safety)
- Tools: checklists
- Optimal resources staff: time → **optimization of workload** across the team
- Experience + option to build up a **network in OTT with KOK and other institutions**

4. Webinar and workshop as a tool: elaboration of a webinar and a workshop nationwide

- Standardized nursing training and consultation is an important contribution to the increasing number of oncological patients under oral therapy
- **Interprofessional webinars** represent a **highly appreciated tool** (including medical and logistic information & networking)

5. Outreach:

- **Checklists, therapy calendars**
- **Publications**
- **Network OTT in KOK**



Sharing Progress
in Cancer Care

THANK YOU

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08/11/23

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