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3 **Study protocol**

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5 Prospektive Studie über den Einfluss von Disney Filmen während Chemotherapie auf die
6 Lebensqualität von gynäkoonkologischen Patientinnen

7 Impact of Disney movies during chemotherapy on QOL of gyneco-oncologic patients, a prospective
8 study

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18 Submitter: Dr. Sophie Pils

19 Assoc. Prof. Dr. Johannes Ott

20 Univ. clinic for gynaecology, MUW

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24 Correspondence:

25 Dr. Sophie Pils

26 Department of Gynecology and Obstetrics

27 Medical University of Vienna

28 A-1090 Vienna

29 Phone: 01-40400-29150

30 Fax: 01-40400-29110

31 E-mail: sophie.pils@meduniwien.ac.at

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33 **Summary**

34 Evaluation of the influence of Disney films on the quality of life of oncological patients.

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36 **Background**

37 The focus of oncological therapies is primarily on efficacy and secondarily on the side effect profile.
38 In recent years, more and more studies on the quality of life (QOL) of oncological patients have been
39 conducted.

40 There are studies that measure QOL under standard therapy (1,2) as well as studies that compare QOL
41 under new drugs with standard therapy (3). Occasionally, alternative therapies were evaluated in
42 addition to known therapies (4). The majority of these studies use the validated EORTC C30
43 (European Organization for Research and Treatment of Cancer-Gynecologic Cancer Group) (5)
44 Quality of life questionnaire to evaluate the quality of life of the patients.

45 Oncological patients in the gynecological oncology department are admitted to the planned
46 chemotherapy ward either in a day clinic or in an in-patient setting. During the morning doctor's visit,
47 patients are proactively asked about side effects and the ECOG Scale of Performance Status (6) is
48 determined. Subsequently, the appropriate chemotherapies are ordered with adequate laboratory
49 values. The patients then wait one to two hours for the therapies. Depending on the schedule,
50 chemotherapy is administered over a period of 3 to 5 hours. After the application of the therapies, the
51 patients, after checking the vital parameters, are discharged into home care the same or next day,
52 depending on the chemotherapy regimen.

53 Supportive measures in pediatric oncology such as "Cliniclows" and similar are socially accepted, but
54 hardly evaluated. Patch Adams also owes us study results (7).

55 Disney films have been evaluated in some small studies on prosocial behavior (8). The influence of
56 Disney films on QOL has not yet been investigated, but it can be assumed that a positive mood
57 remains.

58 Disney films are translated into almost every language and thus studies are internationally comparable
59 with this material.

60

61 **Hypothesis**

62 Disney films have a positive effect on the mood of gynecological patients and improve the subjective
63 quality of life.

64

65 Primary aim of the study:

66 to evaluate whether patients who watch Disney films during chemotherapy show a better QOL after
67 therapy than before.

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69 Secondary study objective:

70 to compare the routinely evaluated allergic reactions and side effects during chemotherapy between
71 the Disney Film Group and the control group

72

73 **Methods**

74 All patients admitted to the ward of the gynecological oncology 16E or 16D for the planned first cycle
75 of chemotherapy (carboplatin/ paclitaxel or carboplatin/pegylated liposomal doxorubicin) will be
76 offered study participation.

77 60 patients can be enrolled until 50 patients have completed the study.

78 Patients are randomized between the two study groups: watching Disney movies or not during the
79 planed six cycles of chemotherapy.

80 Patients in the control group are asked not to watch television or use films on other technical aids. All
81 other activities (listening to music, reading, playing cards, games of any kind, conversations with
82 confidants...) are documented, but are not grounds for exclusion.

83

84 **Inclusion criteria:**

85 - Planned chemotherapy with 6 cycles of carboplatin and paclitaxel or carboplatin and
86 pegylated liposomal doxorubicin at the gynecologic wards 16E and 16D of the Department for
87 Gynecology and gynecologic oncology for Gynecology

88 - Age over 18 years

89 - Sufficient knowledge of German

90

91 **Exclusion criteria:**

92 - All other chemotherapy protocols

93 - Age under 18 years

94 - Insufficient knowledge of German

95

96 After detailed patient education and written informed consent, the patients are included in the study.

97

98 Patients are asked to complete the same questionnaires twice on the same day:

99 - once after ordering but before the application of chemotherapy, and

100 - a second time after the application of chemotherapy during which, depending on the randomization, a
101 Disney film was shown or the patient was not allowed to watch television.

102 This is repeated in each of the 6 planned chemotherapy cycles.

103

104 Duration of study participation: 6 cycles of chemotherapy (depending on laboratory and side effects
105 6x3=18 weeks up to 6 months)

106

107 In addition, the routinely collected side effect profiles and the ECOG status are documented.

108

109 Both The Walt Disney Company, Germany, Switzerland & Austria and Motion Picture Licensing
110 Company, MPLC Austria GmbH were informed about this planned study.

111 A license, which includes a non-commercial license to screen Disney films, will be acquired by Dr.
112 Sophie Pils in case of a positive ethics vote at the beginning of the study.

113 The following films will be shown as part of this study: Lady and the Tramp, The Sword in the Stone,
114 Mary Poppins, The Jungle Book, Aristocats, Robin Hood, Cinderella and The Little Mermaid.

115

116 **Questionnaire**

117 The validated EORTC QLQ-C30 (Appendix 1) and the EORTC QLQ-FA12 (Appendix 2) are used to
118 evaluate QOL and fatigue. In addition, patients are asked to complete the EORTC QLQ - OV28
119 (Appendix 3), EORTC QLQ-CX24 (Appendix 4) or EORTC QLQ-EN 24 (Appendix 5) corresponding
120 to the underlying disease.

121 Answering the questionnaires takes approximately 30 minutes.

122 If any ambiguities arise during the answering of the questionnaire, the patients will be offered help by
123 Dr. Sophie Pils and the medical team of the gynecological department are available.

124

125 **Risk-benefit evaluation**

126 Oncological patients are routinely admitted to hospital every 3 to 4 weeks for 1 to 2 days. During these
127 stays there are longer waiting times for the patients: waiting for the visit, waiting for the
128 chemotherapy, sitting still or lying down while the chemotherapy is administered. In the days
129 following chemotherapy there is fatigue, nausea, blood count disorders, neuropathies.

130 The aim of this study is to interrupt the patients' routine and to evaluate whether this has an influence
131 on their quality of life.

132 It can be assumed that Disney films will have no negative effect on the quality of life of the patients.

133 The subjective quality of life of gynecological patients under chemotherapy is particularly relevant in
134 view of the mostly poor prognosis.

135

136 **Data protection**

137 The collected data is - in the context of anonymization - coded and entered into a Microsoft Excel®
138 table.

139 Only the study team has access to the non-anonymous data.

140

141 **Statistics**

142 For data processing, the patient's initials, date of birth, underlying disease, study group, chemotherapy
143 cycle, allergic reactions, body weight and the prestigious Disney film are provided.

144 The questionnaires are then digitized using Excel (Microsoft, Redmond, Washington, USA) and SPSS
145 (Predictive Analytics Software, SPSS Inc., Chicago, IL, USA). The results (1-7) are then evaluated
146 according to EORTC guidelines.

147 Metric variables are described by mean and standard deviation and compared between groups using
148 the Welch-Satterthwaite t-test. Categorical variables are described by absolute and relative frequencies
149 and compared between groups using Fisher's exact test.

150 Longitudinal outcomes are analyzed with a regression model and a maximum test. These analyses will
151 be made with "R". All other statistical analyses were performed with SPSS software version 25.

152 A p-value of <0.05 is assumed to be significant.

153 **References**

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