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Feasibility of an individualized physical activity intervention in CLL patients receiving ibrutinib +/- venetoclax: Preliminary results from the QOLIBRI Study

QOLIBRI

A study to assess benefits of an individual physical activity Intervention on **Q**uality **O**f **Li**fe in CLL patients who initiated **IBR**ut**I**nib in real-life practice

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Key Takeaway

QOLIBRI preliminary results indicate high commitment of CLL patients under ibrutinib to the remote individualized physical activity (PA) program and activity tracker usage.

Conclusions

Randomized patients showed high rates of adherence and compliance to the remote PA program.

Both investigators and patients reported positive feedback on the PA program and good PRO completion, but PA retention decreased over time. This suggests the need for further strategies to stimulate patient motivation after the first 3 months and ensure long-term participation.

Since the feasibility phase of QOLIBRI meets all the validation criteria, the study will be extended to more patients and more sites as per protocol.

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A. Introduction

- Physical activity (PA) has proven benefits on health-related quality of life (HRQoL), fatigue, and psychological well-being in individuals with chronic diseases and solid tumors (**Delrieu, 2020; Cheville, 2013**). However, evidence in heme cancers, including chronic lymphocytic leukemia (CLL), remains scarce due to limited sample sizes (**Knips, 2019**). In CLL, only one pilot study combining high-intensity interval and resistance training in 15 patients reported a clinically meaningful HRQoL improvement (**Artese, 2022**).
- The World Health Organization recommends that adults engage in at least 150 to 300 minutes of moderate-intensity PA, or 75 to 150 minutes of vigorous-intensity PA, or an equivalent combination of both throughout the week, to achieve substantial health benefits. However, these guidelines were based on questionnaires and did not include goals for step counts. Recent studies using activity trackers suggest that even lower doses of PA are associated with improved HRQoL (**Lee IM, 2025**).
- The primary objective of the QOLIBRI study is to assess the impact of an individualized remote PA intervention, supported by an activity tracker, on HRQoL in patients with CLL undergoing treatment with Bruton tyrosine kinase inhibitors (BTKi), newly treated with ibrutinib (I) for first line or relapsed CLL in monotherapy, in continue combination, or in fixed-duration combination with venetoclax (I+V) according to the SmPC.

Aim of the feasibility assessment

The aim of this interim analysis is to **evaluate the feasibility of the intervention**, focusing on:

- **adherence**,
- **compliance**,
- and **retention**

We report here on the feasibility phase (N=29) of the trial.

B. Methods

B1. Design

- QOLIBRI (ID-RCB: 2023-A01563-42, NCT06299540) is a prospective, randomized, open-label, multicenter low-interventional study in France.
- All participants are equipped with a sleep and physical activity tracker (Withings Pulse HR® connected watch) for 12 months (**Figure 1**).
- The primary outcome is HRQoL at 4 months (**FACT-G** questionnaire). Secondary outcomes and evaluation tools include fatigue (**FACIT**), anxiety and depression (**HAD**), sleep quality (**PSQI**, and activity tracker), physical fitness (six-minute walk test (**6MWT**)), PA (quantified by **step counts** from the activity tracker), and **tolerance** (treatment-related AE).
- A total of 180 patients are expected to have 80% power to detect statistically significant changes in FACT-G scores between the study arms.
- **A feasibility assessment is conducted 12 months after study initiation on approximately 30 patients.**

B2. Feasibility endpoints

- Success of the feasibility assessment is considered if feasibility endpoints meet thresholds of **≥70%** **(Figure 2)**

Figure 2: Feasibility endpoints

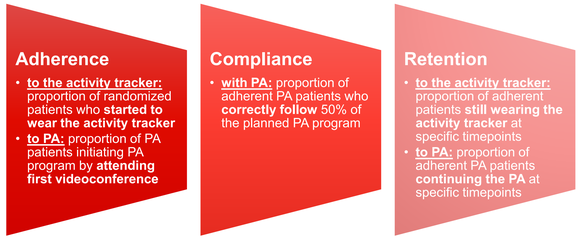
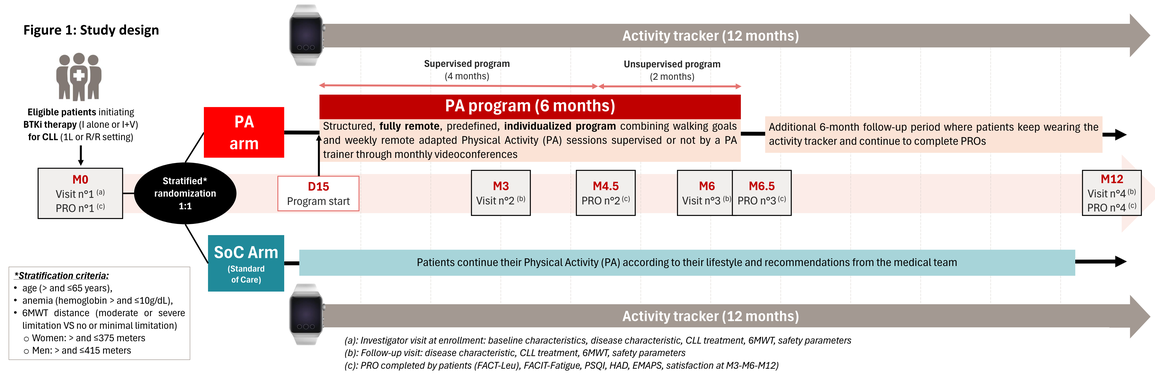


Figure 1: Study design



C. Results

C1. Study conduct

- In the feasibility phase (from 27/05/2024, date of First Patient First Visit to 24/06/2025; date of Last Patient, Last Visit), 29 patients with CLL were enrolled across seven pilot sites, with 13 randomly assigned to the PA arm and 16 to the SoC arm.

C2. Baseline data

- The cohort was predominantly male (62.1%) with a mean age of 65.3 years, 57.1% initiated I alone and 42.9% I+V (**Table 1**).

Table 1: Patient's baseline characteristics

	SoC arm (N=16)	PA arm (N=13)	Total (N=29)
Age at baseline (years), median (Q1-Q3)	66.5 (61-70.5)	68 (59-73)	67 (61-71)
Male, n (%)	6 (37.5%)	12 (92.3%)	18 (62.1%)
BMI (kg/m²), median (Q1-Q3)	24.1 (21.1-27.8)	25.7 (23.8-28.7)	25.5 (22.5-28.7)
Underweight: <18.5	0 (0.0%)	0 (0.0%)	0 (0.0%)
Normal weight: [18.5-25[	9 (56.3%)	5 (38.5%)	14 (48.3%)
Overweight: [25-30[	5 (31.3%)	5 (38.5%)	10 (34.5%)
Obesity: ≥30	2 (12.5%)	3 (23.1%)	5 (17.2%)
Physical activity: 6MWT (walk test)			
No or minimal limitation	15 (93.8%)	13 (100.0%)	28 (96.6%)
Moderate or severe limitation	1 (6.3%)	0 (0.0%)	1 (3.4%)
Type of treatment received, n (%)			
Ibrutinib in monotherapy (I)	11 (68.8%)	5 (41.7%)	16 (57.1%)
Ibrutinib in association (I+V)	5 (31.3%)	7 (58.3%)	12 (42.9%)

C3. Feasibility assessment

Adherence

- 82,8% of patients started to wear the activity tracker (PA: 100%, SoC: 68,8%), based on overall physical activity or sleep data (**Figure 3**).
- 100% of PA patients were considered adherent (attendance to the first videoconference with the PA) (**Figure 4**).

Compliance

- 84.6% of PA patients were considered compliant (with at least 50% of expected PA trainer appointment attended) (**Figure 4**). The mean number of PA trainer appointments was 4.1 (± 1.8) during the overall follow-up (FU), 3.1 (± 1.1) during the supervised period.

Figure 3: Study adherence to the activity tracker

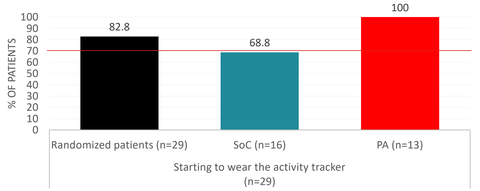
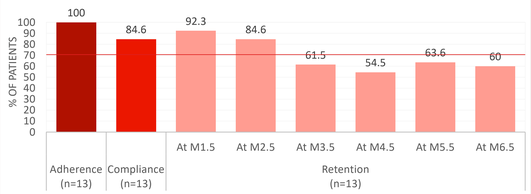


Figure 4: Adherence, compliance, and retention to PA



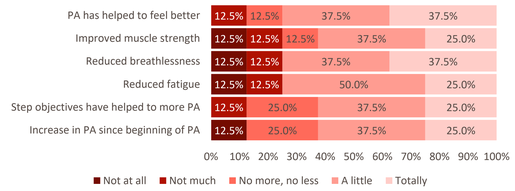
Retention

- To the activity tracker reached 100% in both groups at all timepoints (except M5.5 in SoC arm: 83.3%).
- To PA:
  - Participant retention was considered for 92.5% of PA patients at M1.5 (**Figure 4**). 60% of PA patients were still following the adapted physical activity sessions at the end of feasibility period.
  - The mean duration of the program was 4.8 (± 1.4) months.

C4. Completion and satisfaction

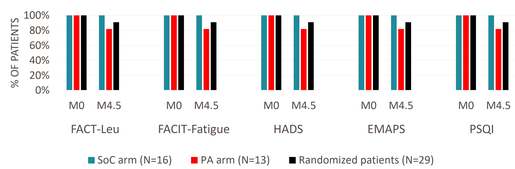
- All sites with patients in the PA arm (n=4) were "highly-satisfied".
- 43% of sites reported little difficulties to motivate patients to participate mainly due to the watch wearing (n=2) or PA sessions difficulty (n=1)
- Patients' feedback on impact of the PA program were good (**Figure 5**).

Figure 5: Patients' feedback related to impact of the program - PA arm (n=8)



- PRO completion rates were 100% at baseline and remained high (≥80%) at after 4.5 months of follow-up (**Figure 6**).

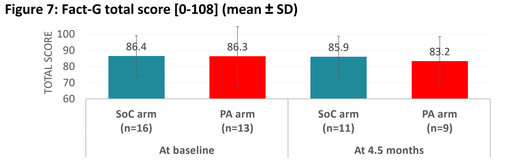
Figure 6: PRO completion



C5. Primary outcome

- Preliminary results of Fact-G total score are presented in **Figure 7**.

Figure 7: Fact-G total score [0-108] (mean ± SD)



Chronic Lymphocytic Leukemia