

A CLINICAL GLOBAL IMPRESSION SEVERITY (CGI-S) SCALE FOR PBC: Results of a focussed training programme



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Introduction

- Primary biliary cholangitis (PBC) is a cholestatic disease which results in significant symptom burden for patients
- The Clinical Global Impression Severity and Change scales for PBC (CGI-S PBC / CGI-C PBC) are recently developed clinical outcome assessments for PBC symptoms
- The validated CGI-S PBC requires clinical experts to rate the severity of symptoms based on detailed interviews of PBC patients
- The CGI-C PBC measures any change in symptoms following an intervention

Aim

 We aimed to deliver a training programme to hepatologists with expertise in PBC in the use and application of the CGI PBC scales

Method

- 29 European clinical expert hepatologists with an expertise in PBC were invited to participate in the dedicated training program on the use of the PBCspecific CGI scales (Figure 1)
- Training involved 3 live virtual sessions using didactic instruction, video modelling, interactive discussion and live interview practice
- Following each live session, trainees viewed, and subsequently rated video recorded PBC patient interviews
- Trainee ratings were compared against pre-determined gold standards, with >80% matched accuracy required to be determined successful, and an approved rater.

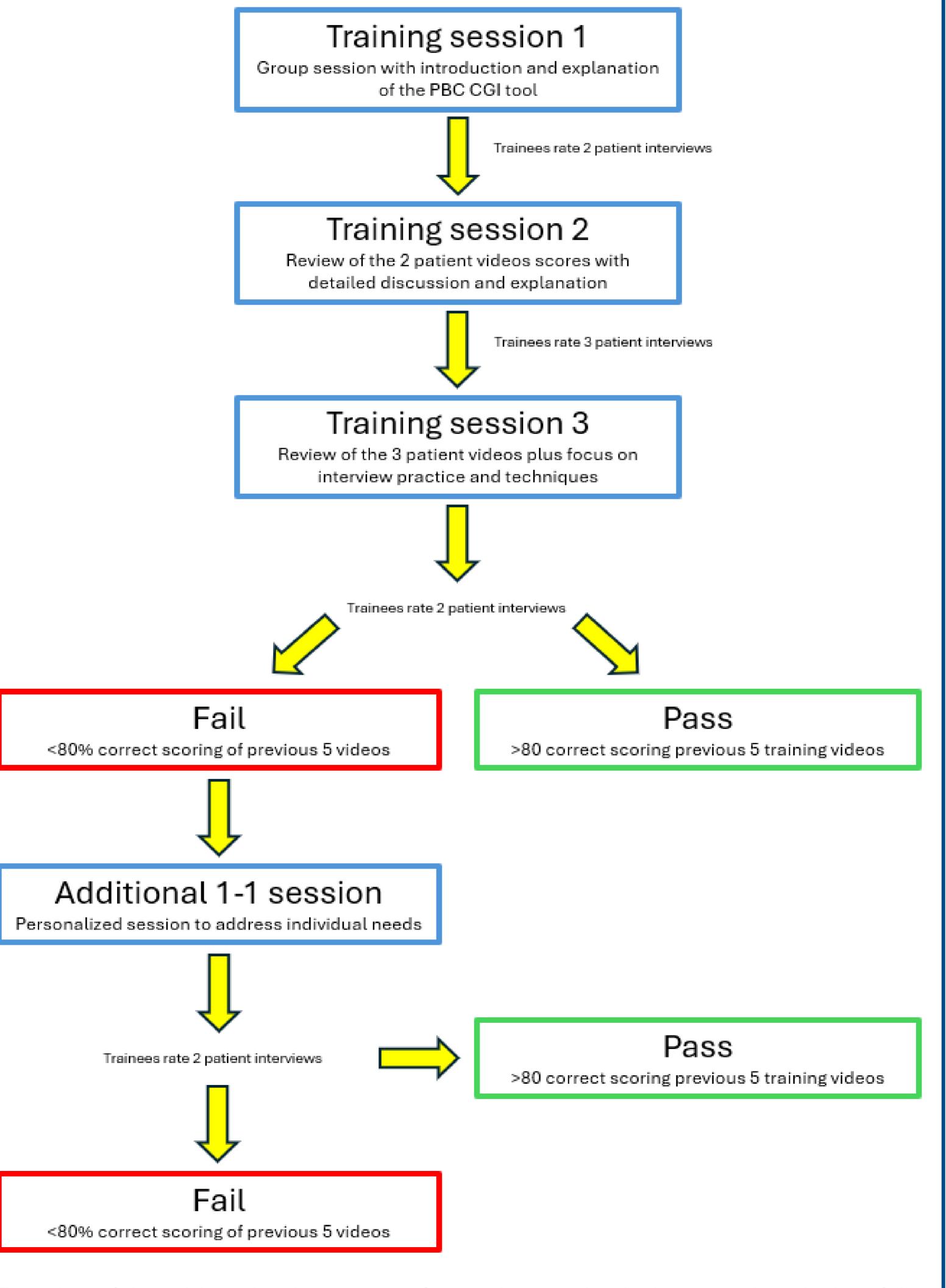
Figure 1: European representation of trainees



Illustration depicting the number of trainees that participated in the training program shown with the number of trainees per country from which they participated

Results

Figure 2: Training program structure



Flow chart of the training education program of expert hepatologists in the use and application of the Clinical Global Impression scales for Primary Biliary Cholangitis

Table 1: Accuracy of trainee ratings

Training cohort	No of trainee per cohort	Rating accuracy achieved	Overall trainee accuracy
A	8	88%	
В	5	86%	
C	8	86%	87%
	4	90%	
E	4	86%	

Table displaying the different trainee cohorts with the total accuracy of trainee ratings of the video recorded PBC patient interviews. Trainee rated patient symptoms using the Clinical Global Impression Severity for PBC scale. Successful rating was deemed as meeting >80% accuracy against pre-determined gold standards.

Conclusions

- This dedicated training program is proven to be effective and successful in training hepatologists to reliably score PBC patients' symptoms using the CGI-S PBC scale
- Approved raters are currently utilising the CGI-S and CGI-C PBC in the symptom assessment of PBC patients in an ongoing phase 2 interventional trial
- This training program complements the PBC specific CGI scales for use as an outcome measure in clinical trials for symptom directed therapies



